(2) *Broiler chickens and cattle.* A tolerance for residues of virginiamycin is not required.

[64 FR 48296, Sept. 3, 1999]

§ 556.760 Zeranol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of zeranol is 0.00125 milligrams per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for residues of zeranol in edible tissues are:

(1) *Cattle.* A tolerance is not needed.

(2) *Sheep.* 20 parts per billion.

(c) *Related conditions of use.* See § 522.2680 of this chapter.

[40 FR 13942, Mar. 27, 1975, as amended at 54 FR 31950, Aug. 3, 1989; 67 FR 6867, Feb. 14, 2002; 70 FR 15759, Mar. 29, 2005]

§ 556.765 Zilpaterol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of zilpaterol is 0.083 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for zilpaterol freebase (the marker residue) is 12 parts per billion (ppb).

(ii) [Reserved]

(2) [Reserved]

[71 FR 53005, Sept. 8, 2006]

§ 556.770 Zoalene.

Tolerances are established for residues of zoalene (3,5-dinitro-*o*-toluamide) and its metabolite 3-amino-5-nitro-*o*-toluamide in food as follows:

(a) In edible tissues of chickens:

(1) 6 parts per million in uncooked liver and kidney.

(2) 3 parts per million in uncooked muscle tissue.

(3) 2 parts per million in uncooked fat.

(b) In edible tissues of turkeys: 3 parts per million in uncooked muscle tissue and liver.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Subpart A—General Provisions

Sec.

Subpart B—Specific New Animal Drugs For Use in Animal Feeds

AUTHORITY: 21 U.S.C. 360b, 371.

SOURCE: 40 FR 13959, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 558.3 Definitions and general considerations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a ''no-residue'' basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required, or are a veterinary feed directive drug.

(2) A ''Type A medicated article'' is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under § 514.105 of this chapter or an index listing granted under § 516.151 of this chapter.

(3) A ''Type B medicated feed'' is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term ''highest continuous use level'' means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(4) A ''Type C medicated feed'' is intended as the complete feed for the animal or may be fed ''top dressed'' (added on top of usual ration) on or offered ''free-choice'' (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(5) A Type B or Type C medicated feed manufactured from a drug component (bulk or ''drum-run'' (dried crude fermentation product)) requires an application approved under § 514.105 of this chapter or an index listing granted under § 516.151 of this chapter.

(6) A ''veterinary feed directive (VFD) drug'' is a new animal drug approved under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) or listed in the index under section 572 of the act for use in or on animal feed. Use of a VFD drug must be under the professional supervision of a licensed veterinarian.

(7) A ''veterinary feed directive'' is a written statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client's animals only in accordance with the directions for use approved or indexed by the Food and Drug Administration (FDA). A veterinarian may issue a VFD only if a valid veterinarian-client-patient relationship exists, as defined in § 530.3(i) of this chapter.

(8) A ''medicated feed'' means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

(9) For the purposes of this part, a ''distributor'' means any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD.

(10) An ''animal production facility'' is a location where animals are raised for any purpose, but does not include the specific location where medicated feed is made.

(11) An ''acknowledgment letter'' is a written communication provided to a distributor by a consignee who is not the ultimate user of medicated feed containing a VFD drug. An acknowledgment letter affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another distributor without receiving a similar written acknowledgment letter.

[51 FR 7392, Mar. 3, 1986, as amended at 52 FR 2682, Jan. 26, 1987; 54 FR 51386, Dec. 15, 1989; 56 FR 19268, Apr. 26, 1991; 64 FR 63206, Nov. 19, 1999; 65 FR 76929, Dec. 8, 2000; 72 FR 69130, Dec. 6, 2007]

§ 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall also conform to the conditions of use provided for in subpart B of this part and in § 558.15 of this chapter.

(d) This paragraph identifies each drug by category, the maximum level of drug in Type B medicated feeds, and the assay limits for the drug in Type A medicated articles and Type B and Type C medicated feeds, as follows:

CATEGORY I

Drug	Assay limits percent [1] type A	Type B maximum (200x)	Assay limits percent [1] type B/C [2]
Amprolium with Ethopabate	94–114	22.75 g/lb (5.0%)	80–120.
Bacitracin methylene disalicylate	85–115	25.0 g/lb (5.5%)	70–130.
Bacitracin zinc	84–115	5.0 g/lb (1.1%)	70–130.
Bambermycins	90–110	800 g/ton (0.09%)	80–120/70–130.
Chlortetracycline	85–115	40.0 g/lb (8.8%)	80–115/70–130.
Coumaphos	95–115	6.0 g/lb (1.3%)	80–120.
Decoquinate	90–105	2.72 g/lb (0.6%)	80–120.
Dichlorvos	100–115	33.0 g/lb (7.3%)	90–120/80–130.
Diclazuril	90–110	182 g/t (0.02%)	85–115/70–120.
Efrotomycin	94–113	1.45 g/lb (0.32%)	80–120.
Erythromycin (thiocyanate salt)	85–115	9.25 g/lb (2.04%)	<20g/ton 70–115/150–50:>20g/ton 75–125.

CATEGORY I—Continued

Drug	Assay limits percent [1] type A	Type B maximum (200x)	Assay limits percent [1] type B/C [2]
Iodinated casein	85–115	20.0 g/lb (4.4%)	75–125.
Laidlomycin propionate potassium	90–110	1 g/lb (0.22%)	90–115/85–115.
Lasalocid	95–115	40.0 g/lb (8.8%)	Type B (cattle and sheep): 80–120; Type C (all): 75–125.
Lincomycin	90–115	20.0 g/lb (4.4%)	80–130.
Melengestrol acetate	90–110	10.0 g/ton (0.0011%)	70–120.
Monensin	85–115	40.0 g/lb (8.8%)	Chickens, turkeys, and quail: 75–125; Cattle: 5–10 g/ton 80–120; Cattle: 10–30 g/ton 85–115; Goats: 20 g/ton 85–115; Liq. feed: 80–120.
Narasin	90–110	7.2 g/lb (1.6%)	85–115/75–125.
Nequinate	95–112	1.83 g/lb (0.4%)	80–120.
Niclosamide	85–120	225g/lb (49.5%)	80–120.
Nystatin	85–125	5.0 g/lb (1.1%)	75–125.
Oleandomycin	85–120	1.125 g/lb (0.25%)	<11.25 g/ton 70–130; >11.25 g/ton 75–125.
Oxytetracycline	90–120	20.0 g/lb (4.4%)	75–125/65–135.
Penicillin	80–120	10.0 g/lb (2.2%)	65–135.
Poloxalene	90–110	54.48 g/lb (12.0%)	Liq. feed: 85–115.
Ractopamine	85–105	2.46 g/lb (0.54%)	80–110/75–125.
Salinomycin	95–115	6.0 g/lb (1.3%)	80–120.
Semduramicin (as semduramicin sodium).	90–110	2.27 g/lb (0.50%)	80–110
Semduramicin (as semduramicin sodium biomass).	90–110	2.27 g/lb (0.50%)	80–120
Tiamulin	113.4 g/lb, 100–108	3.5 g/lb (0.8%)	90–115.
	5 and 10 g/1b, 90–115		70–130.
Tylosin	80–120	10.0 g/lb (2.2%)	75–125.
Virginiamycin	85–115	10.0 g/lb (2.2%)	70–130.
Zoalene	92–104	11.35 g/lb (2.5%)	85–115.

[1] Percent of labeled amount.
[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

CATEGORY II

Drug	Assay limits percent [1] Type A	Type B maximum (100x)	Assay limits percent [1] Type B/C [2]
Amprolium	94–114	11.35 g/lb (2.5%)	80–120.
Apramycin	88–112	7.5 g/lb (1.65%)	80–120.
Arsanilic acid	90–110	4.5 g/lb (1.0%)	85–115/75–125.
Carbadox	90–110	2.5 g/lb (0.55%)	75–125.
Carbarsone	93–102	17.0 g/lb (3.74%)	85–115.
Clopidol	94–106	11.4 g/lb (2.5%)	90–115/80–120.
Famphur	100–110	5.5 g/lb (1.21%)	90–115/80–120.
Fenbendazole	93–113	8.87 g/lb (1.96%)	75–125
Florfenicol	90–110	9.1 g/lb (2.0%)	Swine feed: 85–115 Catfish feed: 80–110 Salmonid feed: 80–110
Halofuginone hydrobromide	90–115	272.0 g/ton (.03%)	75–125.
Hygromycin B	90–110	1,200 g/ton (0.13%)	75–125.
Ivermectin	95–105	1,180 g/ton (0.13%)	80–110.
Maduramicin ammonium	90–110	545 g/ton (.06%)	80–120.
Morantel tartrate	90–110	66.0 g/lb (14.52%)	85–115.
Neomycin	80–120	7.0 g/lb (1.54%)	70–125.
Oxytetracycline	80–120	10.0 g/lb (2.2%)	65–135.
Neomycin sulfate	80–120	100 g/lb (22.0%)	70–125.
Nicarbazin (granular)	90–110	5.675 g/lb (1.25%)	85–115/75–125
Narasin	90–110	5.675 g/lb (1.25%)	85–115/75–125
Nicarbazin (powder)	98–106	5.675 g/lb (1.25%)	85–115/80–120
Nitarsone	90–110	8.5 g/lb (1.87%)	85–120.
Sulfanitran	85–115	13.6 g/lb (3.0%)	75–125.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Novobiocin	85–115	17.5 g/lb (3.85%)	80–120.

CATEGORY II—Continued

Drug	Assay limits percent [1] Type A	Type B maximum (100x)	Assay limits percent [1] Type B/C [2]
Pyrantel tartrate	90–110	36 g/lb (7.9%)	75–125.
Robenidine	95–115	1.5 g/lb (0.33%)	80–120.
Ronnel	85–115	27.2 g/lb (6.0%)	80–120.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Aklomide	90–110	11.35 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Clopidol	94–106	11.35 g/lb (2.5%)	80–120.
Bacitracin methylene disalicylate.	85–115	5.0 g/lb (1.1%)	70–130.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Monensin	90–110	5.5 g/lb (1.2%)	75–125.
Sulfadimethoxine	90–110	5.675 g/lb (1.25%)	85–115/75–125.
Ormetoprim (5/3)	90–110	3.405 g/lb (0.75%)	85–115.
Ormetoprim (5/1)	90–110	17.0 g/lb (3.75%)	85–115.
Sulfaethoxypyridazine	95–105	50.0 g/lb (11.0%)	85–115.
Sulfamerazine	85–115	18.6 g/lb (4.0%)	85–115.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–115	10.0 g/lb (2.2%)	85–125/70–130.
Penicillin	85–115	5.0 g/lb (1.1%)	85–125/70–130.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–115	10.0 g/lb (2.2%)	85–125/70–130.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Tylosin	80–120	10.0 g/lb (2.2%)	75–125.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.715 g/lb (0.60%)	85–120.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.27 g/lb (0.5%)	85–120.
Sulfaquinoxaline	98–106	11.2 g/lb (2.5%)	85–115.
Sulfathiazole	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–125	10.0g/lb (2.2%)	70–130.
Penicillin	80–120	5.0 g/lb (1.1%)	70–130.
Thiabendazole	94–106	45.4 g/lb (10.0%)	>7% 85–115; <7% 90–110.
Tilmicosin	90–110	37.9 g/lb (8.35%)	85–115.
Zilpaterol	90–110	680 g/t (0.075%)	80–110/75–115

[1] Percent of labeled amount.
[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

(e) When drugs from both categories are in combination, the Category II requirements will apply to the combination drug product.

[51 FR 7392, Mar. 3, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.5 Requirements for liquid medicated feed.

(a) *What types of liquid medicated feeds are covered by this section?* This section covers the following types of liquid medicated feed:

(1) Type B feed that is intended for further manufacture of other medicated feeds (§ 558.3(b)(3)) or:

(2) Type C feed that is intended for the following:

(i) Further manufacture of another Type C feed, or

(ii) Top-dressing (adding on top of the usual ration) (§ 558.3(b)(4)).

(b) *How is liquid free-choice medicated feed regulated?* Liquid free-choice medicated feed is covered by this section and by § 510.455.

(c) *What is required for new animal drugs intended for use in liquid feed*? Any new animal drug intended for use in liquid feed must be approved for such use under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) or index listed under section 572 of the act. Such approvals under section 512 of the act must be:

(1) An original NADA,

(2) A supplemental NADA, or

(3) An abbreviated NADA.

(d) *What are the approval requirements under section 512 of the act for new animal drugs intended for use in liquid feed*? An approval under section 512 of the act for a new animal drug intended for use in liquid feed must contain the following information:

(1) Data, or a reference to data in a master file (MF), that shows the relevant ranges of conditions under which the drug will be chemically stable in liquid feed under field use conditions; and

(2) Data, or a reference to data in an MF, that shows that the drug is physically stable in liquid feed under field conditions; or

(3) Feed labeling with recirculation or agitation directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *How are chemical and physical stability data to be submitted?* The data must be submitted as follows:

(1) Directly in the NADA,

(2) By a sponsor, or

(3) To an MF that a sponsor may then reference in its NADA with written consent of the MF holder.

(f) *What will be stated in the published approval for a new animal drug intended for use in liquid feed?* The approval of a new animal drug intended for use in liquid feed as published in this subchapter will include the following requirements:

(1) The formula and/or specifications of the liquid medicated feed, where the owner of this information requests such publication; and/or

(2) A statement that the approval has been granted for a proprietary formula and/or specifications.

(g) *When is a medicated feed mill license required for the manufacture of a liquid medicated feed?* An approved medicated feed mill license is required for the manufacture of the following types of feeds:

(1) All liquid medicated feeds that contain a Category II drug, and

(2) Liquid medicated feeds that contain a Category I drug and use a proprietary formula and/or specifications.

(h) *What measures are in place to prevent certain drugs, approved for use in animal feed or drinking water but not in liquid medicated feed, from being diverted to use in liquid feeds?* Any product containing any form of bacitracin, oxytetracycline, or chlortetracycline, intended for oral administration via animal feed and/or drinking water, and not approved for use in a liquid medicated feed must include in its labeling the following statement: ''FOR USE IN _____ ONLY. NOT FOR USE IN LIQUID MEDICATED FEEDS.'' The blank may be filled in with the words: ''DRY FEEDS'', ''DRINKING WATER'', or ''DRY FEEDS AND DRINKING WATER''.

(i) *Can the labeling provisions of paragraph (h) of this section be waived, and how can I apply for a waiver?* (1) The labeling provisions of paragraph (h) of this section may be waived if there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

(2) To obtain a waiver, you must submit a letter requesting a waiver to the Office of New Animal Drug Evaluation (HFV–100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

(3) The letter must include a copy of the product label; a description of the formulation; and information to establish that the physical, chemical, or other properties of the new animal drug are such that diversion to use in liquid medicated feed is unlikely.

(j) *What else do I need to know about the labeling provisions of paragraph (h) of this section?* The labeling provisions of paragraph (h) of this section may be implemented without prior approval as

provided for in § 514.8(c)(3) of this chapter.

[69 FR 30197, May 27, 2004, as amended at 71 FR 74785, Dec. 13, 2006; 72 FR 69131, Dec. 6, 2007]

§ 558.6 Veterinary feed directive drugs.

(a) What conditions must I meet if I am a veterinarian issuing a veterinary feed directive (VFD)?

(1) You must be appropriately licensed.

(2) You must issue a VFD only within the confines of a valid veterinarian-client-patient relationship (see definition at § 530.3(i) of this chapter).

(3) You must complete the VFD in writing and sign it or it will be invalid.

(4) You must include all of the following information in the VFD or it will be invalid:

(i) You and your client's name, address and telephone and, if the VFD is faxed, facsimile number.

(ii) Identification and number of animals to be treated/fed the medicated feed, including identification of the species of animals, and the location of the animals.

(iii) Date of treatment, and, if different, date of prescribing the VFD drug.

(iv) Approved or index listed indications for use.

(v) Name of the animal drug.

(vi) Level of animal drug in the feed, and the amount of feed required to treat the animals in paragraph (a)(4)(ii) of this section.

(vii) Feeding instructions with the withdrawal time.

(viii) Any special instructions and cautionary statements necessary for use of the drug in conformance with the approval.

(ix) Expiration date of the VFD.

(x) Number of refills (reorders) if necessary and permitted by the approval.

(xi) Your license number and the name of the State issuing the license.

(xii) The statement: ''Extra-label use, (i.e., use of this VFD feed in a manner other than as provided for in the VFD drug approval) is strictly prohibited.''

(xiii) Any other information required by the VFD drug approval regulation.

(5) You must produce the VFD in triplicate.

(6) You must issue a VFD only for the approved or indexed conditions and indications for use of the VFD drug.

(b) What must I do with the VFD if I am a veterinarian?

(1) You must give the original VFD to the feed distributor (directly or through the client).

(2) You must keep one copy of the VFD.

(3) You must give the client a copy of the VFD.

(4) You may send a VFD to the client or distributor by facsimile or other electronic means provided you assure that the distributor receives the original signed VFD within 5 working days of receipt of the facsimile or other electronic order.

(5) You may not transmit a VFD by telephone.

(c) What are the VFD recordkeeping requirements?

(1) The VFD feed distributor must keep the VFD original for 2 years from the date of issuance. The veterinarian and the client must keep their copies for the same period of time.

(2) All involved parties must make the VFD available for inspection and copying by FDA.

(3) All involved parties (the VFD feed distributor, the veterinarian, and the client) must keep VFD's transmitted by facsimile or other electronic means for a period of 2 years from date of issuance.

(4) All involved parties must have a copy of the VFD before distribution of a VFD feed to the ultimate user.

(d) What are the notification requirements if I am a distributor of animal feed containing a VFD drug?

(1) You must notify FDA only once, by letter, that you intend to distribute animal feed containing a VFD drug.

(i) The notification letter must include the complete name and address of each business site from which distribution will occur.

(ii) A responsible person from your firm must sign and date the notification letter.

(iii) You must submit the notification letter to the Center for Veterinary Medicine, Division of Animal Feeds (HFV–220), 7500 Standish Pl., Rockville, MD 20855, prior to beginning your first distribution.

(iv) You must notify the Center for Veterinary Medicine at the above address within 30 days of any change in name or business address.

(2) If you are a distributor who ships an animal feed containing a VFD drug to another consignee-distributor in the absence of a valid VFD, you must obtain an ''acknowledgment letter,'' as defined in § 558.3(b)(11), from the consignee-distributor. The letter must include a statement affirming that the consignee-distributor has complied with ''distributor notification'' requirements of paragraph (d)(1) of this section.

(e) What are the additional recordkeeping requirements if I am a distributor?

(1) You must keep records of receipt and distribution of all medicated animal feed containing a VFD drug.

(2) You must keep these records for 2 years from date of receipt and distribution.

(3) You must make records available for inspection and copying by FDA.

(f) What cautionary statements are required for VFD drugs and animal feeds containing VFD drugs? All labeling and advertising must prominently and conspicuously display the following cautionary statement: ''Caution: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.''

[65 FR 76929, Dec. 8, 2000, as amended at 72 FR 69131, Dec. 6, 2007]

§ 558.15 Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention. etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, or the nitrofuran drugs by no later than September 5, 1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products except the nitrofuran drugs not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, or by December 4, 1973, in the case of nitrofuran drugs, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

(b) Any person interested in developing data which will support retaining approval for such uses of such antibiotic, nitrofuran, and sulfonamide drugs pursuant to section 512(l) of the Federal Food, Drug, and Cosmetic Act shall submit to the Commissioner the following:

(1) By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides; for all other antibiotics by October 17, 1973; and for the nitrofuran drugs by March 4, 1974. The Food and Drug Administration encourages sponsors to consult with the Center for Veterinary Medicine on protocol design and plans for future studies.

(2) By April 20, 1974, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, the sulfonamides, and penicillin assessing the effect of the subtherapeutic use of the drug in feed on the salmonella reservoir in the target animal as compared to that in nonmedicated controls. Failure to complete the salmonella studies for any of these drugs by that time will be grounds for proceeding to immediately withdraw approval.

(3) By April 20, 1975, data satisfying all other specified criteria for safety

and effectiveness, including the effect on the salmonella reservoir for any antibiotic or sulfonamide drugs and by September 5, 1975, for the nitrofuran drugs, approved for subtherapeutic use in animal feeds. Drug efficacy data shall be submitted for any feed-use combination product containing such drug and any feed-use single ingredient antibiotic, nitrofuran, or sulfonamide not reviewed by the National Academy of Sciences—National Research Council, Drug Efficacy Study covering drugs marketed between 1938 and 1962.

(4) Progress reports on studies underway every January 1 and July 1 until completion.

(c) Failure on the part of any sponsor to comply with any of the provisions of paragraph (b) of this section for any of the antibacterial drugs included in paragraph (b)(1) of this section, or interim results indicating a health hazard, will be considered as grounds for immediately proceeding to withdraw approval of that drug for use in animal feeds under section 512(l) of the act in the case of failure to submit required records and reports and under section 512(e) where new information shows that such drug is not shown to be safe.

(d) Criteria based upon the guidelines laid down by the task force may be obtained from the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

(e) Reports as specified in this section shall be submitted to: Food and Drug Administration, Center for Veterinary Medicine, Office of New Animal Drug Evaluation (HFV–100), 7500 Standish Pl., Rockville, MD 20855.

(f) Following the completion of the requirements of paragraphs (a) and (b) of this section and the studies provided for therein:

(1) Those antibiotic, nitrofuran, and sulfonamide drugs which fail to meet the prescribed criteria for subtherapeutic uses but which are found to be effective for the therapeutic purposes will be permitted in feed only for high-level, short-term therapeutic use and only by or on the order of a licensed veterinarian.

(2) Animal feeds containing antibacterial drugs permitted to remain in use for subtherapeutic purposes shall be labeled to include a statement of the quantity of such drugs.

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any Type A medicated article which is produced solely from a Type A article that is in compliance with the requirements of this section: *Provided*, That the Type A medicated article contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the Type A article is approved by regulation in this part.

(1) The following antibacterial Type A articles manufactured by the designated sponsors are eligible for interim marketing based on their compliance with the requirements of this section:

Drug sponsor	Type A article	Species	Use levels	Indications for use
Fermenta Animal Health Co.	Bacitracin methylene disalicylate.	Chicken turkeys, swine, and cattle.	Sec. 558.76	Sec. 558.76.

(2) [Reserved]

[51 FR 8811, Mar. 14, 1986; 51 FR 11014, Apr. 1, 1986, as amended at 51 FR 28547, Aug. 8, 1986; 53 FR 20843, June 7, 1988; 54 FR 37098, Sept. 7, 1989; 54 FR 51386, Dec. 15, 1989; 55 FR 8460, 8462, Mar. 8, 1990; 56 FR 41912, Aug. 23, 1991; 56 FR 64702, Dec. 12, 1991; 57 FR 6476, Feb. 25, 1992; 57 FR 8577, Mar. 11, 1992; 57 FR 14639, Apr. 22, 1992; 58 FR 17515, Apr. 5, 1993; 58 FR 30119, May 26, 1993; 61 FR 51589, Oct. 3, 1996; 64 FR 992, Jan. 7, 1999; 64 FR 37673, July 13, 1999; 71 FR 16221, Mar. 31, 2006; 75 FR 16002, Mar. 31, 2010]

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

§ 558.55 Amprolium.

(a) *Approvals.* Type A medicated articles: 25 percent to No. 016592 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(b) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use*—(1) *Cattle.* It is used as follows:

Amprolium in Grams per Ton	Indications for Use	Limitations	Sponsor
(i) 113.5 to 11, 350; to provide 5 milligrams (mg) per kilogram of body weight per day.	Calves: As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*	Top-dress on or mix in the daily ration. Feed for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; as sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	050604
(ii) 113.5 to 11, 350; to provide 10 mg per kilogram of body weight per day.	Calves: As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*	Top-dress on or mix in the daily ration. Feed for 5 days; as sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. For a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined.	050604

(i) *Amount.* 227 milligrams per 100 pounds (5 milligrams per kilogram) body weight per day.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(*b*) *Limitations.* Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter; as sole source of amprolium. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) *Amount.* 454 milligrams per 100 pounds (10 milligrams per kilogram) body weight per day.

(*a*) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(*b*) *Limitations.* Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter; as sole source of amprolium. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Chickens and turkeys.* It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004% to 0.0125%).		Replacement chickens; development of active immunity to coccidiosis.	Feed as follows—	

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Amprolium grams per ton	*Amprolium grams per ton*	*Amprolium grams per ton*
Severe exposure to coccidiosis	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Arsanilic acid 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
		2. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
(i) 36.3 to 113.5 (0.004% to 0.0125%).	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Bacitracin 100 to 200.	Replacement chickens; development of active immunity to coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate or bacitracin zinc. Feed according to subtable in item (i).	
	Bacitracin methylene disalicylate 4 to 50.	Replacement chickens; development of active immunity to coccidiosis, increased rate of weight gain, and improved feed efficiency. .	Feed according to subtable in item (i); bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter..	046573
	Bacitracin methylene disalicylate 50 plus roxarsone 22.7 to 45.4.	Replacement chickens; development of active immunity to coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed according to subtable in entry (i); bacitracin methylene disalicylate and roxarsone as provided by 046573 in § 510.600(c) of this chapter..	046573

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Chlortetracycline 100 to 200.	Chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Erythromycin 4.6 to 18.5.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.	As erythromycin thiocyanate. Feed according to subtable in item (i).	
	Erythromycin 92.5	1. Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 24 h before slaughter. Feed according to subtable in item (i).	
		2. Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter. Feed according to subtable in item (i).	
	Erythromycin 185	Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter. Feed according to subtable in item (i).	
	Hygromycin B 8 to 12	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).	Feed according to subtable in item (i).	
	Penicillin 2.4 to 50	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.	As procaine penicillin. Feed according to subtable in item (i).	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion, and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
(ii) 72.6 to 113.5 (0.008% to 0.0125%).	.....	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella* only.	Feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%).	.....do	.....do.	
	Bacitracin 100 to 200	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate, or zinc bacitracin.	
	Chlortetracycline 100 to 200.	Chickens; prevention of coccidiosis caused by *E. tenella* only; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Chlortetracycline 200 to 400.	Chickens; prevention of coccidiosis caused by *E. tenella* only; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Hygromycin B 8 to 12	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella* only; control of infestation of large round worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).	Feed according to subtable in item (i).	
	Penicillin 2.4 to 50	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency.	As procaine penicillin.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
(iii) 113.5 (0.0125%) ...	.....	1. Laying chickens; prevention of coccidiosis.	.	
		2. Laying chickens; treatment of coccidiosis.	For moderate outbreaks of coccidiosis; administer for 2 weeks.	
	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; roxarsone as provided by No. 053501 in § 510.600(c) of this chapter, bambermycins by No. 016592; withdraw 5 d before slaughter.	016592
	Bambermycins 1 to 4	Growing turkeys; prevention of coccidiosis; increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole source of amprolium; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(iv) 113.5 to 227 (0.0125% to 0.025%).	.....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.		
		2. Turkeys; prevention of coccidiosis.		
	Arsanilic acid 90 (0.01%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	.....do.	
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	.....do.	
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic.	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improved pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 4 to 50	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As bacitracin methylene disalicylate or bacitracin zinc.	[1] 012769
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.	.....do.	
	Bacitracin 100 to 200	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	.....do.	
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic ry disease (air-sac infection), blue comb (nonspecific infectious enteritis).	As bacitracin zinc.	
	Bacitracin 100 to 500	Turkeys; prevention of coccidiosis; treatment of infectious sinusitis, blue comb (mud fever).	As bacitracin zinc.	
	Bacitracin plus penicillin 100 to 500 (of combination).	.....do	Feed contains 50% to 75% of bacitracin but not more than 125 g penicillin; as procaine penicillin; as bacitracin zinc.	
	Carbarsone 227 to 340.5.	Turkeys; aid in prevention of coccidiosis (*Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis*) and blackhead.	Feed continuously 2 weeks before coccidiosis and blackhead are expected and continue as long as prevention is needed; withdraw 5 days before slaughter; use as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; carbarsone by 046573 in § 510.600(c) of this chapter.	016592

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Chlortetracycline 100 to 200.	Chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens where immunity to coccidiosis is not desired; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As erythromycin thiocyanate.	
	Erythromycin 92.5	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.	
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 24 h before slaughter.	
	Erythromycin 185	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d, do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Hygromycin B 8 to 12	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infestation of large round worms (*Heterakis gallinae*) and capillary worms (*Capillaria obsignata*).	Feed according to subtable in item (i).	
	Penicillin 2.4 to 50	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As procaine penicillin.	
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.	.....do.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	.....do.	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(v) 227 (0.025%)	.....	Laying chickens; treatment of coccidiosis.	For severe outbreaks of coccidiosis; administer for 2 weeks.	

[1] Bacitracin zinc in § 510.600(c) of this chapter.

(3) *Pheasants*. It is used as follows:

(i) *Amount*. 0.0175 percent (159 grams per ton).

(ii) *Indications for use*. For the prevention of coccidiosis in growing pheasants caused by *Eimeria colchici*, *E. duodenalis*, and *E. phasiani*.

(iii) *Limitations*. Feed continuously as sole ration. Use as sole source of amprolium. Fertility, hatchability, and other reproductive data are not available on amprolium in breeding pheasants. Do not use in feeds containing bentonite.

[41 FR 10985, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.55, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.58 Amprolium and ethopabate.

(a) *Specifications*. Type A medicated articles containing:

(1) 25 percent amprolium and 8 percent ethopabate or 5 percent amprolium and 1.6 percent ethopabate;

(2) 25 percent amprolium and 0.8 percent ethopabate or 5 percent amprolium and 0.16 percent ethopabate.

(b) *Approvals*. See No. 016592 in § 510.600(c) of this chapter.

(c) *Special considerations*. Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Related tolerances*. See §§ 556.50 and 556.260 of this chapter.

(e) *Conditions of use*. (1) It is used for chickens as follows:

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) Amprolium 113.5 (0.0125 pct) and ethopabate 3.6 (0.0004 pct).	.....	Broiler chickens as an aid in the prevention of coccidiosis.	Not for laying hens; as sole source of amprolium.	016592
.....	Bambermycins, 1 to 3; plus roxarsone, 22.8 to 34.1.	Broiler chickens: As an aid in the prevention of coccidiosis; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; withdraw 5 d before slaughter; roxarsone provided by No. 046573, bambermycins by No. 016592 in § 510.600(c) of this chapter..	016592
(ii) Amprolium 113.5 (0.0125%) and ethopabate 3.6 (0.0004%).	Bambermycins 2 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain, improved feed efficiency, and pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 016592 in § 510.600(c) of this chapter, roxarsone by No. 046573, bambermycins by No. 016592; withdraw 5 d before slaughter.	016592
	Lincomycin 2 to 4	Broiler chickens; for increase in rate of weight gain; improved feed efficiency; as an aid in the prevention of coccidiosis.	Not for laying chickens; as lincomycin hydrochloride monohydrate; as sole source of amprolium.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Lincomycin 2 to 4 plus roxarsone 45.4 (0.005%).	Broiler chickens; for increase in rate of weight gain; improved feed efficiency and pigmentation; as an aid in the prevention of coccidiosis.	Not for laying chickens; as lincomycin hydrochloride monohydrate; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic.	
	Roxarsone 45.4 (0.005 pct).	Broiler chickens; to aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium; do not use as a treatment for outbreaks of coccidiosis; feed as sole ration from time chickens are placed on litter until the past the time when coccidiosis is ordinarily a hazard; roxarsone as provided by No. 046573 in § 510.600(c) of this chapter; combinations as provided by No. 016592.	
(iii) Amprolium 113.5 (0.0125%) and ethopabate 36.3 (0.004%).	.....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur.	Not for chickens over 16 weeks of age.	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improve pigmentation.	Not for laying hens; withdraw 5 d before slaughter; as sole source of organic arsenic; as erythromycin thiocyanate.	061133
	Bacitracin 4 to 50	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis; as bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; combination as provided by No. 016592 in § 510.600(c) of this chapter.	
	.....	2. Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; improved feed efficiency.	Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for coccidiosis; bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until market weight; combination as provided by No. 046573..	046573

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin 5 to 35 plus roxarsone 34 (0.00375%).	Broiler chickens; for increased rate of weight gain and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 016592 in § 510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter; roxarsone as provided by No. 046573 in § 510.600(c) of this chapter; combination as provided by No. 016592 in § 510.600(c) of this chapter.	
	Bacitracin 20 to 35 plus roxarsone 34 (0.00375%).	Broiler chickens; for increased rate of weight gain, improved feed efficiency, and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 016592 in § 510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter; roxarsone as provided by No. 046573 in § 510.600(c) of this chapter; combination as provided by No. 016592 in § 510.600(c) of this chapter.	
	Bacitracin 10 to 50 plus roxarsone 15.4 to 45.4 (0.0017% to 0.005%).	Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; improved feed efficiency.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 016592 in § 510.600(c) of this chapter; bacitracin zinc as provided by No. 046573 roxarsone as provided by No. 046573 combination as provided by No. 046573.	046573
	Bacitracin 10 plus roxarsone 30 to 45.4 (0.0033% to 0.005%).	Broiler chickens; as an aid in prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina, E. maxima,* and *E. brunetti* is likely to occur; improved feed efficiency and improved pigmentation.	.....do	063238

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bambermycins 1 to 3.	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain, and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium; amprolium, ethopabate as provided by No. 016592 in § 510.600(c) of this chapter, bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain; improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 016592 in § 510.600(c) of this chapter, roxarsone by No. 046573 bambermycins by No. 016592. Withdraw 5 days before slaughter.	016592
	Erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	Not for laying hens; withdraw 24 hours before slaughter; erythromycin thiocyanate.	
	Virginiamycin, 15	Broiler chickens, as an aid in the prevention of coccidiosis where severe exposure to *Eimeria acervulina, E. brunetti,* and *E. maxima* is likely to occur, for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration, do not feed to laying hens, not for chickens over 16 weeks of age, as sole source of amprolium, amprolium and ethopabate as provided by 016592 in § 510.600(c), virginiamycin as provided by 066104.	000069
	Virginiamycin, 5 to 15.	Broiler chickens, as an aid in the prevention of coccidiosis where severe exposure to *Eimeria acervulina, E. brunetti,* and *E. maxima* is likely to occur, for increased rate of weight gain.	.....do.	
(iv) Amprolium 113.5 to 227 (0.0125% to 0.025%) and ethopabate 3.6 (0.0004%).	.....	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.	Not for laying hens.	
	Arsanilic acid 90 (0.01%).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic; not for laying hens.	
		2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation.	Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic; not for laying hens.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 4 to 50	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As bacitracin methylene disalicylate; not for laying hens.	
	Bacitracin 100 to 200.	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	.....do.	
		2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	As zinc bacitracin, not for laying hens.	
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As bacitracin methylene disalicylate; not for laying hens; as sole source of organic arsenic; withdraw 5 d before slaughter.	
	Chlortetracycline 100 to 200.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	
	Erythromycin 92.5 ...	1. For broiler chickens and for replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; not for laying hens.	
		2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 24 h before slaughter; not for laying hens.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Erythromycin 185	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Penicillin 2.4 to 50 ...	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Not for laying hens; as procaine penicillin.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	

(2) [Reserved]

[41 FR 10990, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §558.58, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.59 Apramycin.

(a) *Approvals.* Type A articles to sponsors identified in §510.600(c) of this chapter as follows:

(1) 000986 for 75 grams apramycin (as apramycin sulfate) per pound for use as in paragraph (d)(1) of this section.

(2) [Reserved]

(b) [Reserved]

(c) *Related tolerances.* See §556.52 of this chapter.

(d) *Conditions of use*—(1) *Swine*—(i) *Amount.* 150 grams per ton.

(ii) *Indications for use.* For control of porcine colibacillosis (weanling pig scours) caused by susceptible strains of *Escherichia coli*.

(iii) *Limitations.* Use for 14 days. Withdraw 28 days before slaughter.

(2) [Reserved]

[51 FR 9190, Mar. 18, 1986]

§ 558.62 Arsanilic acid.

(a) *Approvals.* Type A medicated articles to sponsors in §510.600(c) of this chapter as follows:

(1) To 015565: 20, 50, and 100 percent for use as in the table in paragraph (c)(1), entry (ii), item 1; entry (ii), item 2; entry (iv); entry (vi); and entry (vii) of this section.

(2) To 015565: 20 percent for use as in paragraph (c)(1), entry (i); entry (ii), item 3 of this section.

(3) To 061133: 90 grams per pound arsanilic acid and 4.6 grams per pound erythromycin equivalents as erythromycin thiocyanate for use as in paragraph (c)(1), entry (iii); 90 grams per pound arsanilic acid and 9.25 grams per pound erythromycin equivalents as erythromycin thiocyanate for use as in paragraph (c)(1), entry (v).

(b) *Related tolerances.* See §556.60 of this chapter.

(c) *Conditions of use.* (1) It is used as follows:

Arsanilic acid in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 45 to 90		1. Growing chickens: For growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 days before slaughter; as sole source of organic arsenic.	015565
		2. Growing turkeys: For growth promotion and feed efficiency; improving pigmentation.	.....do	015565
		3. Growing swine: For increased rate of weight gain and improved feed efficiency.	.....do	015565
(ii) 90		Swine: As an aid in control of swine dysentery (hemorrhagic enteritis, bloody dysentery).	.....do	015565
(iii)	Erythromycin 4.6	Chickens; growth promotion and feed efficiency; improving pigmentation..	As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic..	012487
(iv)	Erythromycin 4.6 to 18.5.	Chickens; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic.	15565
(v)	Erythromycin 9.25	Chickens; growth promotion and feed efficiency; improving pigmentation..	As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic..	012487
(vi)	Erythromycin 92.5	1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 2 days before stress and 3 to 6 days after stress; withdraw 5 days before slaughter; as sole source of organic arsenic.	015565
		2. Chickens; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic.	015565
(vii)	Erythromycin 185	Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 5 to 8 days; do not use in birds producing eggs for food purposes; withdraw 5 days before slaughter; as sole source of organic arsenic.	15565

(2) Arsanilic acid may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium and ethopabate in accordance with § 558.58.

(iii) Bacitracin zinc in accordance with § 558.78.

(iv) Bacitracin and zoalene in accordance with § 558.680.

(v) Zoalene in accordance with § 558.680.

[41 FR 10992, Mar. 15, 1976, as amended at 42 FR 18617, Apr. 8, 1977; 51 FR 7395, Mar. 3, 1986; 51 FR 33897, Sept. 24, 1986; 54 FR 18281, Apr. 28, 1989; 56 FR 19268, Apr. 26, 1991; 60 FR 39847, Aug. 4, 1995; 66 FR 14074, Mar. 9, 2001; 66 FR 57873, Nov. 19, 2001]

§ 558.76 Bacitracin methylene disalicylate.

(a) *Approvals.* Type A medicated articles: 10, 25, 30, 40, 50, 60, or 75 grams per pound to 046573 in § 510.600(c) of this chapter.

(b) *Special considerations.* The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use.* (1) It is used as follows:

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50		Chickens, turkeys, and pheasants; increased rate of weight gain and improved feed efficiency [1].		046573
(ii) 5 to 20		Quail not over 5 weeks of age; increased rate of weight gain and improved feed efficiency [1].		046573
(iii) 10 to 25		Chickens; for increased egg production and improved feed efficiency for egg production.	For first 7 months of production	046573
(iv) 10 to 30		Swine: for increased rate of weight gain and improved feed efficiency.	For growing and finishing swine	046573
	Chlortetracycline approximately 400, varying with body weight and food consumption to provide 10 milligrams per pound of body weight per day.	Swine; for increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed for not more than 14 days; bacitracin methylene disalicylate provided by No. 046573; chlortetracycline provided by Nos. 046573 and 048164 in § 510.600(c) of this chapter.	046573 048164
		Swine; for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.	Feed for not more than 14 days; chlortetracycline and BMD as provided by 046573 in § 510.600(c) of this chapter.	046573
(v) [Reserved]				
(vi) 50		Broiler chickens; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium spp.* or other organisms susceptible to bacitracin.		046573
		Replacement chickens; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration	046573
(vii)–(viii) [Reserved]				
(ix) 100 to 200		Broiler chickens; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.		046573
		Replacement chickens; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 g/t).	046573
(x) 200		Turkeys; as an aid in the control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin methylene disalicylate.		046573
		Quail; for the prevention of ulcerative enteritis in growing quail due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate.	From Type A medicated articles containing 25, 40, or 50 grams of bacitracin methylene disalicylate. Feed continuously as the sole ration.	046573

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xi) 250		1. Growing/Finishing Swine: For control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery but where signs of the disease have not yet occurred; or following an approved treatment of the disease condition.	As the sole ration. Not for use in swine weighing more than 250 pounds. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.	046573
		2. Pregnant sows: For control of clostridial enteritis caused by *C. perfringens* in suckling piglets.	As the sole ration. Feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.	.....

[1] These conditions are NAS/NRC reviewed and found effective. Applications for these uses may not require effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) It is used as bacitracin methylene disalicylate in feed for animals as follows:

(i) *Amount*. 70 milligrams per head per day.

(*a*) *Indications for use*. Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(*b*) *Limitations*. Administer continuously throughout the feeding period.

(ii) *Amount*. 250 milligrams per head per day.

(*a*) *Indications for use*. Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(*b*) *Limitations*. Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.

(3) Bacitracin methylene disalicylate may also be used with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Carbarsone (not USP) as in § 558.120.

(iv) Decoquinate alone and with roxarsone as in § 558.195.

(v) Diclazuril alone and with roxarsone as in § 558.198.

(vi) Fenbendazole as in § 558.258.

(vii) Halofuginone hydrobromide alone and with roxarsone as in § 558.265.

(viii) Hygromycin B as in § 588.274.

(ix) Ivermectin as in § 558.300.

(x) Lasalocid sodium alone and with roxarsone as in § 558.311.

(xi) Monensin alone and with roxarsone as in § 588.355.

(xii) Narasin alone and with roxarsone as in § 558.363.

(xiii) Nicarbazin alone or with narasin or roxarsone or with narasin and roxarsone as in § 558.366.

(xiv) Nitarsone as in § 558.369.

(xv) Robenidine alone and with roxarsone as in § 558.515.

(xvi) Salinomycin alone and with roxarsone as in § 558.550.

(xvii) Semduramicin alone and with roxarsone as in § 558.555.

(xviii) Zoalene alone and with arsanilic acid or roxarsone as in § 558.680.

[41 FR 10993, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.76, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.78 Bacitracin zinc.

(a) *Specifications*. Type A medicated articles containing bacitracin zinc equivalent to 10, 25, 40, or 50 grams per pound bacitracin.

(b) *Approvals*. See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.70 of this chapter.

(d) *Conditions of use*. (1) It is used as follows:

Bacitracin zinc in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50		Chickens: for increased rate of weight gain and improved feed efficiency.	Growing chickens	046573
(ii) 4 to 50		Turkeys and pheasants: for increased rate of weight gain and improved feed efficiency.	Growing turkeys and pheasants	046573
(iii) 5 to 20		Quail; for increased rate of weight gain and improved feed efficiency.	Growing quail; feed as the Type C feed to starting quail through 5 weeks of age.	046573
(iv) 10 to 25		Laying chickens; improved feed efficiency and increased egg production.		046573
(v) 10 to 50		Swine; increased rate of weight gain and improved feed efficiency.	Growing and finishing swine	046573
(vi) 20		Growing-finishing swine; increased rate of weight gain.	In Type C feed	046573
(vii) 20 to 40		Growing-finishing swine; improved feed efficiency.	....do	046573

(2) It is used in feed for growing cattle at 35 to 70 milligrams per head per day as follows:

(i) To aid in stimulating growth and improving feed efficiency.

(ii) For increased rate of weight gain and improved feed efficiency; see sponsor 046573.

(3) It may be used as approved in combination with:

(i) Amprolium alone and with roxarsone as in § 558.55.

(ii) Amprolium and ethopabate alone and with roxarsone as in § 558.58.

(iii) Carbarsone as in § 558.120.

(iv) Clopidol alone and with roxarsone as in § 558.175.

(v) Decoquinate alone and with roxarsone as in § 558.195.

(vi) Hygromycin B alone and with penicillin as in § 558.274.

(vii) Lasalocid sodium alone or with roxarsone as in § 558.311.

(viii) Monensin alone and with roxarsone as in § 558.355.

(ix) Naracin as in § 558.363.

(x) Nitarsone as in § 558.369.

(xi) Robenidine as in § 558.515.

(xii) Salinomycin alone and with roxarsone as in § 558.550.

(xiii) Zoalene alone and with arsanilic acid or roxarsone as in § 558.680.

[41 FR 10994, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.78, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.95 Bambermycins.

(a) *Approvals.* To sponsors identified by drug labeler codes in § 510.600(c) of this chapter for use of bambermycins Type A medicated articles as bambermycins activity per pound in paragraph (d) of this section as follows:

(1) To 016592: 2, 4, and 10 grams for use as in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section.

(2) To 016592: 0.4 gram for use as in paragraph (d)(2) of this section.

(3) [Reserved]

(4) To Nos. 012286, 016968, and 017790: 0.4 and 2 grams for use as in paragraph (d)(2) and 2 grams for use as in paragraph (d)(3) of this section.

(5) To 016592: 10 grams to make 40 to 800 grams per ton Type B feed for use as in paragraph (d)(4) of this section.

(b) *Special considerations.* (1) Bambermycins liquid Type B feeds may be manufactured from dry bambermycins Type A articles. The liquid Type B feeds must have a pH of 3.8 to 7.5, moisture content of 30 to 45 percent.

(2) The expiration date for the liquid Type B feed is 8 weeks after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 1 week after date of manufacture.

(c) [Reserved]

(d) *Conditions of use*—(1) *Broiler chickens.* It is used as follows:

(i) *Amount per ton.* 1 to 2 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration.

(ii) [Reserved]

(2) *Growing-finishing swine.* It is used as follows:

(i) *Amount per ton.* 2 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration.

(ii) *Amount per ton.* 2 to 4 grams.

(*a*) *Indications for use.* For increased rate of weight gain.

(*b*) *Limitations.* Feed continuously as sole ration.

(3) *Growing turkeys.* It is used as follows:

(i) *Amount per ton.* 1 to 2 grams.

(*a*) *Indications for use.* For improved feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* 2 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration.

(4) *Cattle*—(i) *Amount per ton.* 1 to 4 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously in a Type C medicated feed at a rate of 10 to 20 milligrams of bambermycins per head per day. Liquid Type B feeds containing bambermycins may be used in the preparation of dry complete ration Type C feeds.

(ii) *Amount per ton.* 2 to 40 grams.

(*a*) *Indications for use.* For increased rate of weight gain.

(*b*) *Limitations.* Feed continuously to pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) at a rate of 10 to 40 milligrams of bambermycins per head per day in at least 1 pound and not more than 10 pounds of Type C medicated feed. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(iii) Used as a free-choice Type C medicated loose mineral feed for pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) as follows:

(*a*) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6–01–080	42.50
Sodium chloride (salt)	6–04–152	20.10
Calcium carbonate (38% calcium)	6–01–069	15.24
Corn distillers dried grains w/solubles	5–28–236	9.57
Magnesium oxide	6–02–756	5.15
Vitamin and trace mineral premix *	.....	3.72
Mineral oil	.....	1.00
Yeast (primary dehydrated yeast)	7–05–533	0.75
Bambermycins Type A article (10 g/lb)	.....	0.60
Iron oxide	6–02–431	0.50
Magnesium sulfate (67%)	6–02–758	0.32
Selenium premix (270 mg/lb) *	.....	0.21
Copper sulfate	6–01–720	0.18
Potassium sulfate (0.33%)	6–06–098	0.16

*Content of vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(*b*) *Amount per ton.* 120 grams.

(*c*)*Indications for use.* For increased rate of weight gain.

(*d*) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Daily bambermycins intakes in excess of 20 mg/head/day have not

been shown to be more effective than 20 mg/head/day.

(iv) Use free-choice Type C medicated feeds for pasture cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers) as follows:

(*a*) *Amount.* Feed continuously to provide 10 to 40 milligrams of bambermycins per head per day.

(*b*) *Indications for use.* For increased rate of weight gain.

(*c*) *Limitations.* Each use in a free-choice Type C medicated feed must be the subject of an approved new animal drug application (NADA) or supplemental NADA as required by 21 CFR 510.455. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

(5) Bambermycins may also be used in combination with:

(i) Amprolium alone or with roxarsone as in § 558.55.

(ii) Amprolium and ethopabate alone or with roxarsone as in § 558.58.

(iii) Diclazuril as in § 558.198.

(iv) Halofuginone as in § 558.265.

(v) Lasalocid alone or with roxarsone as in § 558.311.

(vi) Monensin alone or with roxarsone as in § 558.355.

(vii) Narasin alone or with nicarbazin or roxarsone as in § 558.363.

(viii) Nicarbazin as in § 558.366.

(ix) Salinomycin alone or with roxarsone as in § 558.550.

(x) Zoalene alone or with roxarsone as in § 558.680.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.95, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.105 [Reserved]

§ 558.115 Carbadox.

(a) *Approvals.* Type A medicated articles: 2.2. percent (10 grams per pound) to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.100 of this chapter.

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* 10–25 grams (0.0011–0.00275 percent).

(i) *Indications for use.* For increase in rate of weight gain and improvement of feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(2) *Amount per ton.* 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(3) *Amount per ton.* Carbadox 50 grams (0.0055 percent) plus pyrantel tartrate, 96 grams (0.0106 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Do not feed to swine over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in complete feeds containing less than 15 percent crude protein.

(4) *Amount.* Carbadox, 10 to 25 grams per ton of feed; plus oxytetracycline, 10 milligrams per pound of body weight.

(i) *Indications for use.* For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Feed continuously for 7 to 14 days. Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 45164, Oct. 1, 1975; 40 FR 57798, Dec. 12, 1975; 42 FR 761, Jan. 4, 1977; 51 FR 7396, Mar. 3, 1986; 63 FR 59216, Nov. 3, 1998; 66 FR 47963, Sept. 17, 2001; 69 FR 51173, Aug. 18, 2004]

§ 558.120 Carbarsone (not U.S.P.).

(a) *Approvals.* Type A medicated articles: (1) 37.5 percent to 046573 in § 510.600(c) of this chapter.

(2) 25 percent carbarsone and 5 grams per pound bacitracin (as bacitracin methylene disalicylate) to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.60 of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) It is used for turkeys as follows:

(i) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent).

(*a*) *Indications for use.* As an aid in the prevention of blackhead.

(*b*) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(ii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarsone plus 10 grams per ton bacitracin from bacitracin methylene disalicylate.

(*a*) *Indications for use.* As an aid in the prevention of blackhead; for increased rate of weight gain.

(*b*) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarsone plus 4 to 45 grams per ton bacitracin from bacitracin zinc.

(*a*) *Indications for use.* As an aid in the prevention of blackhead, increased rate of weight gain, and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration. Withdraw 5 days before slaughter. As sole source of organic arsenic; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter.

(iv) *Grams per ton.* 227 carbarsone, plus 1 or 4 grams per ton bambermycins.

(*a*) *Indications for use.* As an aid in the prevention of blackhead; and for increased rate of weight gain (4 grams per ton bambermycins) or improved feed efficiency (1 gram per ton bambermycins).

(*b*) *Limitations.* Feed continuously 2 weeks before blackhead is expected and continue as long as prevention is needed. Withdraw 5 days before slaughter. As sole source of organic arsenic. Bambermycins provided by No. 046573 in § 510.600(c) of this chapter.

(2) Carbarsone (not U.S.P.) may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Zoalene in accordance with § 558.680.

(ii) Amprolium as in § 558.55.

[41 FR 10995, Mar. 15, 1976, as amended at 42 FR 18617, Apr. 8, 1977; 46 FR 46797, Sept. 22, 1981; 48 FR 2758, Jan. 21, 1983; 51 FR 7396, Mar. 3, 1986; 52 FR 2687, Jan. 26, 1987; 53 FR 20843, June 7, 1988; 57 FR 7652, Mar. 4, 1992; 61 FR 515, Jan. 8, 1996; 61 FR 18082, Apr. 24, 1996; 62 FR 61011, Nov. 14, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 71 FR 27956, May 15, 2006]

§ 558.128 Chlortetracycline.

(a) *Specifications.* Type A medicated articles containing either chlortetracycline calcium complex equivalent to chlortetracycline hydrochloride or, for products intended for use in milk replacer, chlortetracycline hydrochloride.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 046573, 048164, and 066104: 50 to 100 grams per pound (g/lb) of Type A medicated article.

(2) No. 012286: 50, 90, or 100 grams per pound of Type A medicated article.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *Special considerations.* (1) In milk replacers or starter feed; include on labeling the warning: ''A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.''

(2) Manufacture for use in free-choice feeds as in paragraph (e)(4)(iii) of this section must conform to § 510.455 of this chapter.

(3) When manufactured for use as in paragraph (e)(5)(iv) of this section, include on labeling the warning: ''Psittacosis, avian chlamydiosis, or ornithosis is a reportable communicable disease, transmissible between wild and domestic birds, other animals, and man. Contact appropriate public health and regulatory officials.''

(e) Conditions of use—(1) *Chickens*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Chickens: For increased rate of weight gain and improved feed efficiency..	.....	046573.
		.....	
		Do not feed to chickens producing eggs for human consumption..	012286, 046573, 048164, 066104.
(ii) 100 to 200 g/ton	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline..	1. Feed continuously for 7 to 14 d.	046573.
		.....	
		2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption..	012286, 046573, 048164, 066104.
(iii) 200 to 400 g/ton	Chickens: For the control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline..	1. Feed continuously for 7 to 14 d.	046573.
		.....	
		2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption..	012286, 046573, 048164, 066104.
(iv) 500 g/ton	Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline..	1. Feed for 5 d; 0-day withdrawal time when formulated from AUREOMYCIN Type A medicated articles or Type B medicated feeds under NADA 48–761..	046573.
		2. Feed for 5 d; withdraw 24 h prior to slaughter; do not feed to chickens producing eggs for human consumption..	012286, 046573, 048164, 066104.

(2) *Turkeys*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing turkeys: For increased rate of weight gain and improved feed efficiency..	Do not feed to turkeys producing eggs for human consumption..	012286, 046573, 048164, 066104.
(ii) 200 g/ton	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	012286, 046573, 048164, 066104.
(iii) 400 g/ton	1. Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to chlortetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	012286, 046573, 048164, 066104.
.....	.....	.....	
	2. Turkey poults not over 4 weeks of age: For reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline..		012286, 046573, 048164, 066104.
(iv) 25 mg/lb of body weight.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to chlortetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	012286, 046573, 048164, 066104.

(3) *Swine*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton	Growing swine: For increased rate of weight gain and improved feed efficiency..	.....	012286, 046573, 048164, 066104.
(ii) 50 to 100 g/ton	Swine: For reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group *E. Streptococci* susceptible to chlortetracycline..	.....	012286, 046573, 048164, 066104.
(iii) 400 g/ton	Breeding swine: For the control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to chlortetracycline..	Feed continuously for not more than 14 d..	012286, 046573, 048164, 066104.
(iv) 10 mg/lb of body weight.	1. Swine: For the treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline..	Feed approximately 400 g/t, varying with body weight and feed consumption to provide 10 mg/lb per day. Feed for not more than 14 d; withdraw 5 d prior to slaughter for sponsor 012286..	012286, 046573, 048164, 066104.
.....	.....	.....	
	2. Swine: For the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline..	Feed for not more than 14 d.	046573.

(4) *Cattle*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 0.1 mg/lb of body weight daily..	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency..	See paragraph (d)(1) of this section. ..	012286, 046573, 048164, 066104.
(ii) 0.5 mg/lb of body weight daily..	Beef cattle (over 700 lb); control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline..	Withdraw 48 h prior to slaughter. To sponsor Nos. 046573 and 048164: zero withdrawal time..	012286, 046573, 048164, 066104.
(iii) 0.5 to 2.0 mg/lb of body weight daily..	Beef cattle and nonlactating dairy cattle: As an aid in the control of active infection of anaplsmosis caused by *A. marginale* susceptible to chlortetracycline..	In free-choice cattle feeds such as feed blocks or salt-mineral mixes manufactured from approved Type A articles. See paragraph (d)(2) of this section..	046573.
(iv) 10 mg/lb of body weight daily.	1. Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline..	Feed approximately 400 g/ton, varying with body weight and feed consumption to provide 10 mg/lb per day. Treat for not more than 5 d; in feed including milk replacers; withdraw 10 d prior to slaughter. To sponsor No. 048164: zero withdrawal time. See paragraph (d)(1) of this section..	012286, 048164, 066104.
.....	2. Calves (up to 250 lb): For the treatment of bacterial enteritis caused by *E. coli* susceptible to chlortetracycline..	See paragraph (d)(1) of this section. ..	012286, 046573, 048164, 066104.
(v) 500 to 4,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline..	Feed continuously for not more than 5 days to provide 10 mg/lb body weight per day. To sponsor No. 046573 under NADA 046–699: 24-h withdrawal time. To sponsor No. 046573 under NADA 048–761: zero withdrawal time..	046573.
(vi) 4,000 to 20,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline..	As a top dress, varying with body weight and feed consumption, to provide 10 mg/lb per day. Treat for not more than 5 days. See paragraph (d)(1) of this section..	046573.
(vii) 25 to 70 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency..	See paragraph (d)(1) of this section. ..	012286, 046573, 048164, 066104.

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(viii) 70 mg/head/day	Growing cattle (over 400 lb): For increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses..	See paragraph (d)(1) of this section. ..	012286, 046573, 048164, 066104.
(ix) 350 mg/head/day	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline..	Withdraw 48 h prior to slaughter. To sponsor No. 046573 under NADA 046–699: 48-h withdrawal time. To sponsor No. 046573 under NADA 048–761 and No. 048164: zero withdrawal time..	012286, 046573, 048164, 066104.
.....	2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline..	Withdraw 48 h prior to slaughter. To sponsor No. 046573 under NADA 046–699: 48-h withdrawal time. To sponsor No. 046573 under NADA 048–761 and No. 048164: zero withdrawal time..	012286, 046573, 048164, 066104.

(5) *Minor species*. It is used as follows:

Chlortetracycline amount	Indications for use	Limitations	Sponsor
(i) 20 to 50 g/ton	Growing sheep; increased rate of weight gain and improved feed efficiency..	.....	046573, 048164, 066104.
(ii) 80 mg/head/day	Breeding sheep; reducing the incidence of (vibrionic) abortion caused by *Campylobacter fetus* infection susceptible to chlortetracycline..	.....	046573, 048164, 066104.
(iii) 200 to 400 g/ton	Ducks: For the control and treatment of fowl cholera caused by *P. multocida* susceptible to chlortetracycline..	Feed in complete ration to provide from 8 to 28 mg/lb of body weight per day depending upon age and severity of disease, for not more than 21 d. Do not feed to ducks producing eggs for human consumption..	046573.
(iv) 10 mg/g of finished feed daily..	Psittacine birds (cockatoos, macaws, and parrots) suspected or known to be infected with psittacosis caused by *Chlamydia psittaci* sensitive to chlortetracycline..	Feed continuously for 45 d; each bird should consume daily an amount of medicated feed equal to one fifth of its body weight.. ..... See paragraph (d)(3) of this section. ..	046573.

(6) It is used as a free-choice, loose mineral Type C feed as follows:

(i) *Specifications*.

Ingredient	Percent	International Feed No.
Dicalcium Phosphate	46.20	6–26–335
Sodium Chloride (Salt)	15.00	6–04–152
Magnesium Oxide	10.67	6–02–756
Cottonseed Meal	10.00	5–01–625
Trace Mineral/Vitamin Premix[1]	3.80	
Calcium Carbonate	3.50	6–01–069
Dried Cane Molasses	3.00	4–04–695
Potassium Chloride	2.00	6–03–755
Mineral Oil	2.00	8–03–123
Iron Oxide	0.50	6–02–431
Chlortetracycline Type A medicated article (90 gram/lb)	3.33	

[1]Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(ii) *Amount*. 6,000 grams per ton.

(iii) *Indications for use*. Beef and nonlactating dairy cattle: As an aid in the control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline.

(iv) *Limitations*. Feed continuously on a free-choice basis at a rate of 0.5 to 2.0 mg chlortetracycline per head per day.

(v) *Sponsor*. See No. 046573 in § 510.600(c) of this chapter.

(7) *Chlortetracycline*. It may be used in accordance with this section in combinations as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium plus ethopabate in accordance with § 558.58.

(iii) Bacitracin methylene disalicylate in accordance with § 558.76.

(iv) Clopidol in accordance with § 558.175.

(v) Decoquinate in accordance with § 558.195.

(vi) Hygromycin B in accordance with § 558.274.

(vii) Laidlomycin in accordance with § 558.305.

(viii) Lasalocid in accordance with § 558.311.

(ix) Monensin in accordance with § 558.355.

(x) Robenidine hydrochloride in accordance with § 558.515.

(xi) Roxarsone in accordance with § 558.530.

(xii) Salinomycin alone or with roxarsone in accordance with § 558.550.

(xiii) Tiamulin in accordance with § 558.600.

(xiv) Zoalene in accordance with § 558.680.

[41 FR 10995, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.128, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.140 Chlortetracycline and sulfamethazine.

(a) *Approvals*. Type A medicated articles: 35 grams of chlortetracycline per pound with 7.7 percent (35 grams) of sulfamethazine to Nos. 046573 and 048164 in § 510.600(c) of this chapter.

(b) *Related tolerances*. See §§ 556.150 and 556.670 of this chapter.

(c) It is used in feed for beef cattle as follows:

(1) *Amount per head per day*. Chlortetracycline, 350 milligrams plus sulfamethazine, 350 milligrams.

(2) *Indications for use*. Aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

(3) *Limitations*. Feed for 28 days; withdraw 7 days prior to slaughter.

[61 FR 35954, July 9, 1996, as amended at 64 FR 15684, Apr. 1, 1999; 66 FR 46706, Sept. 7, 2001; 68 FR 22294, Apr. 28, 2003; 69 FR 62407, Oct. 26, 2004]

§ 558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.

(a) *Approvals*. Type A medicated articles: (1) 20 grams of chlortetracycline per pound, 4.4 percent (20 grams) of sulfamethazine, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound to 046573 in § 510.600(c) of this chapter.

(2) 40 grams of chlortetracycline per pound, 8.8 percent of sulfamethazine, and penicillin procaine equivalent in activity to 20 grams of penicillin per pound to 046573 and 048164 in § 510.600(c) of this chapter.

(b) *Specifications*. (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

(3) Type C medicated feed contains in each ton, 100 grams of chlortetracycline, 50 grams of penicillin as procaine penicillin, and 100 grams of sulfamethazine.

(c) *Related tolerances*. See §§ 556.150, 556.510, and 556.670 of this chapter.

(d) *Conditions of use*. (1) It is administered to swine in a Type C feed for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery); prevention of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds.

(2) Withdraw 15 days prior to slaughter.

[40 FR 13959, Mar. 27, 1975, as amended at 43 FR 19385, May 5, 1978; 47 FR 39814, Sept. 10, 1982; 48 FR 30615, July 5, 1983; 51 FR 7396, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 56 FR 14019, Apr. 5, 1991; 61 FR 18082, Apr. 24, 1996; 62 FR 14300, Mar. 26, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 68 FR 47237, Aug. 8, 2003; 69 FR 62407, Oct. 26, 2004]

§ 558.155 Chlortetracycline, sulfathiazole, penicillin.

(a) *Approvals*. Type A medicated articles: (1) 20 grams of chlortetracycline hydrochloride, 4.4 percent (20 grams) sulfathiazole, and procaine penicillin equivalent to 10 grams of penicillin per pound to No. 046573 in § 510.600(c) of this chapter.

(2) 40 grams of chlortetracycline hydrochloride, 8.8 percent (40 grams) sulfathiazole and procaine penicillin equivalent in activity to 20 grams of

penicillin per pound to No. 046573 in § 510.600(c) of this chapter.

(b) *Specifications.* (1) The antibiotic substance refers to the antibiotic or feed-grade antibiotic.

(2) The antibiotic activities are expressed in terms of the appropriate antibiotic standards.

(c) *Related tolerances.* See §§ 556.150, 556.510, and 556.690 of this chapter.

(d) *Conditions of use.* It is used for swine as follows:

(1) *Amount per ton.* Chlortetracycline, 100 grams plus penicillin, 50 grams plus sulfathiazole, 100 grams.

(2) *Indications for use.* For reduction of incidence of cervical abscesses. Treatment of bacterial enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery). Maintenance of weight gains in the presence of atrophic rhinitis. Swine 10 pounds of body weight to 6 weeks post-weaning: Increased rate of weight gain and improved feed efficiency. Swine 6 to 16 weeks postweaning: Increased rate of weight gain.

(3) *Limitations.* For swine raised in confinement (dry-lot) or on limited pasture. Feed as sole ration. Withdraw 7 days prior to slaughter.

MINIMUM AMOUNT OF TYPE C FEED WHICH THE ANIMAL SHOULD CONSUME

Type of feed	Approximate body weight in pounds	Minimum desired daily feed intake in pounds
Prestarter (up to 6 weeks postweaning)	20	1
Starter (up to 6 weeks postweaning)	50	1½
Grower (6–16 weeks postweaning)	80	2
Finisher (6–16 weeks postweaning)	150	3

[40 FR 13959, Mar. 27, 1975, as amended at 51 FR 7397, Mar. 3, 1986; 51 FR 28547, Aug. 8, 1986; 52 FR 2684, Jan. 26, 1987; 61 FR 2415, Jan. 26, 1996; 62 FR 35077, June 30, 1997; 62 FR 67725, Dec. 30, 1997; 63 FR 11599, Mar. 10, 1998; 66 FR 46706, Sept. 7, 2001; 67 FR 21171, Apr. 30, 2002]

§ 558.175 Clopidol.

(a) *Specifications.* Type A medicated article containing 25 percent clopidol.

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* It is used as follows:

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 113.5		Broiler chickens and re-placement chickens intended for use as caged layers: As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Do not feed to chickens over 16 weeks of age.	016592
(2) 113.5	Bacitracin methylene disalicylate 4 to 50.	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain.	Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age; bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.	016592
(3) 113.5	Bacitracin 4 to 25 plus roxarsone 45.4.	Broiler chickens: As in paragraph (d)(1) of this section; for growth promotion, feed efficiency; improved pigmentation, and increased rate of weight gain.	Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate or bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter.	046573, 016592

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(4) 113.5	Bacitracin zinc 5 to 25.	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter.	046573, 016592
(5) 113.5	Chlortetracycline 100 to 200.	Broiler and replacement chickens: As in paragraph (d)(1) of this section; for control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Feed continuously as sole ration from the time chicks are placed in floor pens for 7 to 14 days.	016592
(6) 113.5	Lincomycin 2 to 4	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Do not feed to chickens over 16 weeks of age; as lincomycin hydrochloride monohydrate.	000009
(7) 113.5	Roxarsone 45.4	Broiler and replacement chickens intended for use as caged layers: As in paragraph (d)(1) of this section; for growth promotion, feed efficiency; and improved pigmentation.	Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.	016592
(8) 227	.....	Broiler and replacement chickens intended for use as caged layers: As in paragraph (d)(1) of this section.	Feed continuously as the sole ration; feed up to 16 weeks of age if intended for use as caged layers; withdraw 5 days before slaughter if given at the level of 0.025 percent in feed or reduce level to 0.0125 percent 5 days before slaughter.	016592
(9) 113.5 or 227	.....	Turkeys: As an aid in the prevention of leucocytozoonosis caused by *Leucocytozoon smithi*.	For turkeys grown for meat purposes only; feed continuously as the sole ration at 0.0125 or 0.025 percent clopidol depending on management practices, degree of exposure, and amount of feed eaten; withdraw 5 days before slaughter.	016592

[68 FR 17882, Apr. 14, 2003, as amended at 72 FR 60551, Oct. 25, 2007; 74 FR 61028, Nov. 23, 2009]

§ 558.185 Coumaphos.

(a) *Specifications*. Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos.

(b) *Approvals*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000859 for use of Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos as in paragraphs (e)(2) and (e)(3) of this section.

(2) No. 051311 for use of Type A medicated articles containing 1.12 percent coumaphos as in paragraph (e)(1) of this section.

(c) *Related tolerances*. See 40 CFR 180.189.

(d) *Special considerations*. Labeling shall bear the following caution statement: ''The active ingredient coumaphos is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.'' Also, see § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Beef and dairy cattle*—(i) *Amount*. 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days. Should conditions warrant, repeat treatment at 30-day intervals.

(ii) *Indications for use*. Control of gastrointestinal roundworms (*Haemonchus* spp., *Ostertagia* spp., *Cooperia* spp., *Nematodirus* spp., *Trichostrongylus* spp.).

(iii) *Limitations*. Feed in the normal grain ration to which the animals are accustomed, but not in rations containing more than 0.1 percent coumaphos. Do not feed to animals less than 3 months old. Do not feed to sick animals or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks. Do not feed in conjunction with

oral drenches or with feeds containing phenothiazine.

(2) *Laying chickens*—(i) *Amount.* Coumaphos 27.2 grams per ton (0.003 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common round worm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In Type C feed; administer continuously as the total feed ration for 14 days; when reinfection occurs, treatment may be repeated but not sooner than 3 weeks after the end of the previous treatment; do not feed to chickens within 10 days of vaccination or other conditions of stress; treatment of colored breeds of commercial layers should be avoided while in production since these breeds appear to be more sensitive to coumaphos than white breeds; as sole medication; medications in general should be avoided while birds are approaching peak production; such interruption of normal feeding practices may upset the flock and lower egg production; diagnosis by competent personnel is essential; flock condition and production records should be carefully evaluated prior to treatment.

(3) *Replacement pullets*—(i) *Amount.* Coumaphos 36.3 grams per ton (0.004 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common roundworm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In Type C feed; administer before the onset of production; diagnosis by competent personnel is essential; administer continuously as total feed ration for from 10 to 14 days; do not feed to chickens under 8 weeks of age nor within 10 days of vaccination or other conditions of stress; if birds are maintained on contaminated litter or exposed to infected birds, a second 10 to 14 day treatment is recommended but not sooner than 3 weeks after the end of the previous treatment; as sole medication; if reinfection occurs after production begins, repeat treatment as recommended for laying flocks.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 1463, Jan. 7, 1977; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 61 FR 34729, July 3, 1996; 69 FR 70056, Dec. 2, 2004; 70 FR 32489, June 3, 2005; 75 FR 24394, May 5, 2010]

§ 558.195 Decoquinate.

(a) *Specifications.* Type A medicated article containing 6 percent decoquinate.

(b) *Approvals.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.170 of this chapter.

(d) *Special considerations.* (1) Bentonite should not be used in decoquinate feeds.

(2) Type A medicated articles may be used to manufacture dry or liquid Type B cattle (including veal calf), sheep, and goat feeds as in paragraphs (e)(2) and (e)(3) of this section.

(3) Type C cattle feeds may be manufactured from decoquinate liquid Type B feeds having a pH between 5.0 to 6.5 and containing a suspending agent to maintain a viscosity of not less than 500 centipoises.

(e) *Conditions of use.* It is used as follows:

(1) *Chickens.*

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27.2	.....	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti*..	Do not feed to laying chickens.	046573
(ii) 27.2	Bacitracin methylene disalicylate 4 to 50.	Broiler chickens: As in paragraph (e)(1)(i) of this section; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter..	046573

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iii) 27.2	Bacitracin zinc 10 to 50.	Broiler chickens: As in paragraph (e)(1)(ii) of this section..	Feed continuously as sole ration; do not feed to laying chickens. Bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter..	046573
(iv) 27.2	Bacitracin zinc 12 to 50 plus roxarsone 11 to 45.	Broiler chickens: As in paragraph (e)(1)(ii) of this section..	Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic..	046573
.....	.....	.....	Bacitracin zinc and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter..	
(v) 27.2	Bacitracin methylene disalicylate 50 and roxarsone 22.7 to 45.4.	Broiler chickens: As in paragraph (e)(1)(ii) of this section; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for improved pigmentation..	Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days before slaughter. Not for use in breeder chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of drinking water may result in leg weakness or paralysis.. Bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter..	046573
(vi) 27.2	Chlortetracycline 100 to 200.	Chickens: As in paragraph (e)(1)(i) of this section; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline..	Feed continuously for 7 to 14 days; do not feed to chickens producing eggs for human consumption..	046573
(vii) 27.2	Chlortetracycline 200 to 400.	Chickens: As in paragraph (e)(1)(i) of this section; and for control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline..	As in paragraph (e)(1)(vi) of this section..	046573
(viii) 27.2	Lincomycin 2	Broiler chickens: As in paragraph (e)(1)(ii) of this section..	Feed as sole ration; do not feed to laying chickens; lincomycin provided by No. 000009 in § 510.600(c) of this chapter..	000009 046573
(ix) 27.2	Roxarsone 45.4	Broiler chickens: As in paragraph (e)(1)(ii) of this section; and for improving pigmentation..	Do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic..	046573

(2) *Cattle.*

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8	.....	Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Feed Type C feed or milk replacer to provide 22.7 milligrams (mg) per 100 pounds (lb) of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section..	046573

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 12.9 to 90.8 ...	Chlortetracycline 500 to 4,000..	Calves, beef, and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by *Escherichia coli*; and for treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline..	Feed Type C feed to provide 22.7 mg decoquinate and 1 gram chlortetracycline per 100 lb body weight per day for not more than 5 days. When consumed, feed 22.7 mg decoquinate per 100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141–147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter..	046573
(iii) 12.9 to 90.8 ..	Monensin 5 to 30	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; and for improved feed efficiency..	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day and 50 to 360 mg of monensin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. Also see paragraph (d)(1) of this section and § 558.355(d)(8). Monensin as provided by No. 000986 in § 510.600(c) of this chapter..	046573

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iv) 13.6 to 27.2 ..	Chlortetracycline approximately 400 (varying with body weight and feed consumption to provide 10 mg/lb of body weight per day).	Calves, beef and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by *E. coli*; and for treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline..	Feed Type C feed to provide 22.7 mg decoquinate and 1 gram (g) chlortetracycline per 100 lb body weight (0.5 mg/kg) per day for not more than 5 days. Type C feed may be prepared from Type B feed containing 535.8 to 5,440 g/ton decoquinate and 6,700 to 80,000 g/ton chlortetracycline. When consumed, feed 22.7 mg decoquinate per 100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from chlortetracycline Type A medicated articles under NADA 141–147 and ANADA 200–359. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185. Do not feed to calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by Nos. 046573 and 048164 in § 510.600(c) of this chapter..	046573 048164
(v) 13.6 to 27.2 ...	Monensin 5 to 30 plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for improved feed efficiency; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*..	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day, 50 to 360 mg of monensin per head per day, and 60 to 90 mg of tylosin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Also see paragraph (d)(1) of this section and § 558.355(d)(8). Monensin and tylosin as provided by No. 000986 in § 510.600(c) of this chapter..	046573
(vi) 90.9 to 535.7	.....	Cattle (including ruminating and nonruminating calves and veal calves): As in paragraph (e)(2)(i) of this section..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lb of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section..	046573

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(vii) 90.9 to 535.7	Chlortetracycline 4,000 to 20,000..	Calves, beef, and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by *Escherichia coli*; and for treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg decoquinate and 1 gram chlortetracycline per 100 lb body weight per day for not more than 5 days. When consumed, feed 22.7 mg decoquinate per 100 lb body weight per day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141–147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter..	046573

(3) *Minor species.*

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8	.....	1. Young sheep: For the prevention of coccidiosis caused by *Eimeria ovinoidalis, E. crandallis, E. parva,* and *E. bakuensis*..	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food..	046573
.....	.....	2. Young goats: For the prevention of coccidiosis caused by *E. christenseni* and *E. ninakohlyakimovae*..	Feed Type C feed or milk replacer at a rate to provide 22.7 mg per 100 lb of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for food..	
(ii) 90.9 to 535.7	.....	1. Young sheep: As in item 1 of paragraph (e)(3)(i) of this section..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food..	046573

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
.....	.....	2. Young goats: As in item 2 of paragraph (e)(3)(i) of this section..	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for food..	

[67 FR 72370, Dec. 5, 2002; 68 FR 15372, Mar. 31, 2003; 69 FR 26499, May 13, 2004; 69 FR 52816, Aug. 30, 2004; 69 FR 62407, Oct. 26, 2004; 69 FR 67264, Nov. 17, 2004; 70 FR 2567, Jan. 14, 2005]

§ 558.198 Diclazuril.

(a) *Specifications*. Type A medicated article containing 0.2 percent diclazuril.

(b) *Approvals*. See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.185 of this chapter.

(d) *Conditions of use*. (1) *Chickens*. For chickens it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 part per million (ppm)).	.....	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati*), and *E. maxima*. Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima*..	Feed continuously. Not for use in hens producing eggs for human food..	016592
(ii) 0.91 (1 ppm) ..	Bacitracin methylene disalicylate 4 to 50.	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency..	As in item (i) of this table. Bacitracin methylene disalicylate provided by 046573..	016592
(iii) 0.91 (1 ppm).	Bacitracin methylene disalicylate 50 plus roxarsone 22.7 to 45.4.	Broiler chickens: As in item (i) of this table; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; for increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed continuously as the sole ration throughout growing period. Use as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Not for use in hens producing eggs for human consumption. Withdraw 5 days before slaughter. Bacitracin methylene disalicylate and roxarsone provided by No. 046573 in § 510.600(c) of this chapter..	016592

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(iv) 0.91 (1 ppm).	Bacitracin methylene disalicylate 100 to 200 plus roxarsone 22.7 to 45.4.	Broiler chickens: As in item (i) of this table; as an aid in the control of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin; for increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed continuously as the sole ration throughout growing period. Start at first clinical signs of disease; vary dosage of bacitracin based on severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton (g/ton). Use as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Not for use in hens producing eggs for human consumption. Withdraw 5 days before slaughter. Bacitracin methylene disalicylate and roxarsone provided by No. 046573 in § 510.600(c) of this chapter..	016592
(v) 0.91 (1 ppm)	Bambermycins 1 to 2	Broiler chickens: As in item (i) of this table); for increased rate of weight gain and improved feed efficiency..	As in item (i) of this table. Bambermycins provided by 057926..	016592
(vi) 0.91(1 ppm) ..	Roxarsone 22.7 to 45.4.	Broiler chickens: As in item (i) of this table; for increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed continuously as the sole ration throughout growing period. Use as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Not for use in hens producing eggs for human consumption. Withdraw 5 days before slaughter.. Roxarsone provided by No. 046573 in § 510.600(c) of this chapter..	046573
(vii) 0.91 (1 ppm)	Virginiamycin 5	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency..	As in item (i) of this table; Virginiamycin provided by 066104..	016592
(viii) 0.91 (1 ppm)	Virginiamycin 5 to 15	Broiler chickens: As in item (i) of this table; for increased rate of weight gain..	As in item (i) of this table. Virginiamycin provided by 066104..	016592

(2) *Turkeys*. For turkeys it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 ppm) ..	.....	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. gallopavonis* and *E. meleagrimitis*..	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption..	016592
(ii) 0.91 (1 ppm).	Bacitracin methylene disalicylate 4 to 50..	Growing turkeys: As in paragraph (d)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency..	As in paragraph (d)(2)(i) of this section. Bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter..	016592
(iii) 0.91 (1 ppm).	Bambermycins 1 to 2	Growing turkeys: As in paragraph (d)(2)(i) of this section; for improved feed efficiency..	As in paragraph (d)(2)(i) of this section. Bambermycins provided by No. 057926 in § 510.600(c) of this chapter..	016592
(iv) 0.91 (1 ppm).	Bambermycins 2	Growing turkeys: As in paragraph (d)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency..	As in paragraph (d)(2)(i) of this section. Bambermycins provided by No. 057926 in § 510.600(c) of this chapter..	016592

[64 FR 35923, July 2, 1999, as amended at 65 FR 50134, Aug. 17, 2000; 66 FR 47962, 47963, Sept. 17, 2001; 66 FR 62917, Dec. 4, 2001; 67 FR 34830, May 16, 2002; 67 FR 47257, July 18, 2002; 67 FR 48549, July 25, 2002; 69 FR 9947, Mar. 3, 2004; 72 FR 60552, Oct. 25, 2007]

§ 558.205 Dichlorvos.

(a) *Approvals.* Type A medicated articles: 3.1 and 9.6 percent to 000010 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) Dichlorvos is to be included in meal or mash or mixed with feed in crumble form only after the crumble feed has been manufactured. Do not mix in feeds to be pelleted nor with pelleted feed. Do not soak the feed or administer as wet mash. Feed must be dry when administered. Do not use in animals other than swine. Do not allow fowl access to feed containing this preparation or to feces from treated animals.

(2) Dichlorvos is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. If human or animal poisoning should occur, immediately consult a physician or a veterinarian. Atropine is antidotal.

(3) Labeling for Type A articles and Type B feeds must include a statement that containers or materials used in packaging such Type A articles and Type B feeds are not to be reused and all such packaging materials must be destroyed after the product has been used.

(c) *Related tolerances.* See § 556.180 of this chapter.

(d) *Conditions of use.* It is used in feed for swine as follows:

(1) *Amount per ton.* Dichlorvos, 348 grams (0.0384 percent).

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*) and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For swine up to 70 pounds body weight, feed as sole ration for 2 consecutive days. For swine from 70 pounds to market weight, feed as sole ration at the rate of 8.4 pounds of feed per head until the medicated feed has been consumed. For boars, open or bred gilts, and sows, feed as sole ration at the rate of 4.2 pounds per head per day for 2 consecutive days.

(2) *Amount per ton.* Dichlorvos, 479 grams (0.0528 percent).

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For boars, open or bred gilts, and sows, feed as sole ration at the rate of 6 pounds per head for one feeding.

(3) *Amount per ton.* Dichlorvos, 334–500 grams (0.0366–0.0550 percent).

(i) *Indications for use.* An aid in improving litter production efficiency by increasing pigs born alive, birth weights, survival to market, and rate of weight gain. Treatment also removes and controls mature, immature and/or fourth stage larvae of whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum supp.*) large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) occurring in the gastrointestinal tract of the sow or gilt.

(ii) *Limitations.* For pregnant swine; mix into a gestation feed to provide 1,000 milligrams per head daily during last 30 days of gestation.

[40 FR 13959, Mar. 27, 1975, as amended at 40 FR 50258, Oct. 29, 1975; 48 FR 46515, Oct. 13, 1983; 51 FR 7397, Mar. 3, 1986; 51 FR 28547, Aug. 8, 1986; 52 FR 2684, Jan. 26, 1987; 62 FR 35077, June 30, 1997]

§ 558.235 Efrotomycin.

(a) *Approvals.* Type A medicated article: 14.5 grams per pound to 050604 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Swine*—(i) *Amount.* 3.6 grams per ton.

(A) *Indications for use.* For improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration. Not to be used in swine weighing more than 250 pounds.

(ii) *Amount.* 3.6 to 14.5 grams per ton.

(A) *Indications for use.* For increased rate of weight gain.

(B) *Limitations.* Feed continuously as sole ration. Not to be used in swine weighing more than 250 pounds.

(2) [Reserved]

[57 FR 38442, Aug. 25, 1992, as amended at 62 FR 63271, Nov. 28, 1997]

§ 558.248 Erythromycin thiocyanate.

(a) *Approvals.* Type A medicated articles: (1) 2.2 percent to 061623 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) 5 and 10 percent to 061623 for use in paragraphs (d)(1)(i) and (ii) of this section.

(b) *Special considerations.* The levels of antibiotic are expressed in terms of erythromycin master standard. One gram of erythromycin thiocyanate is equivalent to 0.925 gram of erythromycin master standard.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Condition of use.* (1) It is used as follows:

Erythromycin thiocyanate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 18.5		Chickens; growth promotion and feed efficiency.		061623
(ii) 9.25 to 18.5		Turkeys; growth promotion and feed efficiency.	For turkeys not over 12 weeks of age.	061623
(iii) 9.25 to 64.75		Swine; increase in weight gain, improved feed efficiency in starter pigs (9.25 to 64.75) and grower-finishing pigs (9.25).	Starter ration for animals up to 35 lb body weight.	061623
(iv) 18.5		Laying chickens; aids in increasing egg production.		061623
(v) 92.5		1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.	061623
		2. Chickens; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 24 h before slaughter.	
		3. Turkeys; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress.	
(vi) 185		1. Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	061623
		2. Turkeys; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes.	061623

(2) In feed for feedlot beef cattle at 37 milligrams per head per day as an aid in stimulating growth and improving feed efficiency.

(3) Erythromycin thiocyanate may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium and ethopabate in accordance with § 558.58.

(iii) Arsanilic acid in accordance with § 558.62.

(iv) Zoalene in accordance with § 558.680.

[41 FR 10999, Mar. 15, 1976, as amended at 45 FR 56799, Aug. 26, 1980; 49 FR 31281, Aug. 6, 1984; 51 FR 7397, Mar. 3, 1986; 52 FR 2684, Jan. 26, 1987; 54 FR 12189, Mar. 24, 1989; 66 FR 14074, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 558.254 Famphur.

(a) *Approvals.* Type A medicated articles: 13.2 and 33.3 percent to 000061 in § 510.600(c) of this chapter.

(b) *Special considerations.* Famphur is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after

treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(c) *Related tolerances.* See § 556.273 of this chapter.

(d) *Conditions of use.* It is used in the feed for cattle as follows:

(1) *Amount.* 1.1 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs and as an aid in control of sucking lice.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 30 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

(2) *Amount.* 2.3 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 10 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

[41 FR 11000, Mar. 15, 1976, as amended at 51 FR 7397, Mar. 3, 1986; 57 FR 7652, Mar. 4, 1992; 62 FR 55161, Oct. 23, 1997; 62 FR 61626, Nov. 19, 1997]

§ 558.258 Fenbendazole.

(a) *Specifications.* Type A medicated articles: 4 percent (18.1 grams per pound (g/lb)), 8 percent (36.2 g/lb), and 20 percent (90.7 g/lb) fenbendazole.

(b) *Approvals.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Turkeys.*

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
14.5 (16 parts per million).	.....	Growing turkeys: For the removal and control of gastrointestinal worms: roundworms, adult and larvae (*Ascaridia dissimilis*); cecal worms, adult and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead).	Feed continuously as the sole ration for 6 days. For growing turkeys only.	000061

(2) *Swine.*

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 300 (to provide 9 milligrams per kilogram (mg/kg) of body weight) given over a 3- to 12-day period.	.....	For the removal and control of: Adult stage lungworms (*Metastrongylus apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms (*Ascaris suum*); adult stage nodular worms (*Oesophagostomum dentatum, O. quadrispinulatum*); adult stage small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); adult and larvae kidney worms (*Stephanurus dentatus*).	Feed as sole ration	000061
(ii) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 20	As in paragraph (e)(2)(i) of this section; for increased rate of gain in growing-finishing swine.	Feed as sole ration. Do not feed to swine that weigh more than 250 pounds (lbs); lincomycin as provided by 000009 in § 510.600(c) of this chapter.	000061

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 40	As in paragraph (e)(2)(i) of this section; for control of swine dysentery in animals on premises with a history of swine dysentery, but where symptoms have not yet occurred.	Feed as sole ration. Do not feed to swine that weigh more than 250 lbs.; lincomycin as provided by 000009 in § 510.600(c) of this chapter.	000061
(iv) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 100	As in paragraph (e)(2)(i) of this section; for the treatment of swine dysentery.	Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 lbs.; lincomycin as provided by 000009 in § 510.600(c) of this chapter.	000061
(v) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 200	As in paragraph (e)(2)(i) of this section; for reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.	Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 pound (lb); lincomycin as provided by 000009 in § 510.600(c) of this chapter.	000061
(vi) 10 to 300 (to provide 9 mg/kg of body weight).	Bacitracin methylene disalicylate 10 to 30.	Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency.	Feed as sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	046573
(vii) 10 to 300 (to provide 9 mg/kg of body weight).	Bacitracin methylene disalicylate 250.	1. Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.	1. Growing/finishing swine: Feed as sole ration. Not for use in growing and finishing swine that weigh more than 250 lbs. Diagnosis of swine dysentery should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	046573
.....	.....	2. Pregnant sows: As in paragraph (e)(2)(i) of this section; for control of clostridial enteritis in suckling pigs caused by *Clostridium perfringens*.	2. Pregnant sows: Feed as sole ration. Diagnosis of clostridial enteritis should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	

(3) *Cattle.*

Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) 5 mg/kg body weight (2.27 mg/lb)	Dairy and beef cattle: For the removal and control of: Lungworms (*Dictyocaulus viviparus*); Stomach worms: barberpole worms (*Haemonchus contortus*), brown stomach worms (*Ostertagia ostertagi*), small stomach worms (*Trichostrongylus axei*); Intestinal worms: hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia oncophora* and *C. punctata*); Bankrupt worms (*Trichostrongylus colubriformis*); and Nodular worms (*Oesophagostomum radiatum*).	Feed as the sole ration or as a top dress for one day. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	000061
(ii) [Reserved]		.....	

(iii) *Free-choice feeds*—(A) *Amount*. 5 mg/kg body weight (2.27 mg/lb), including the following formulations:

Ingredient[1]	Percent	International Feed No.
(*1*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	59.00	6–04–152
Monosodium phosphate	31.16	6–04–288
Dried cane molasses	3.12	4–04–695
Zinc sulfate	0.76	6–05–556
Copper sulfate	0.45	6–01–720
Fenbendazole 20% Type A article	5.51	n/a
(*2*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	35.93	6–04–152
Dicalcium phosphate (18.5% P)	32.44	6–00–080
Calcium carbonate (38% Ca)	15.93	6–01–069
Magnesium oxide (56% Mg)	10.14	6–02–756
Zinc sulfate	1.47	6–05–556
Mineral oil	1.00	8–03–123
Dried cane molasses (46% sugars)	0.98	4–04–695
Potassium iodide	0.01	6–03–759
Fenbendazole 20% Type A article	2.10	n/a
(*3*) Free-choice, liquid Type C feed:		
Cane molasses[2]	80.902	4–13–251
Water	9.36	n/a
Urea solution, 55%	7.05	5–05–707
Phosphoric acid 75% (feed grade)	2.00	6–03–707
Xantham gum	0.20	8–15–818
Trace minerals	0.20	n/a
Vitamin premix	0.01	n/a
Fenbendazole 20% Type A article	0.278	n/a

[1]The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the manufacturer for other free-choice cattle feeds. Formulation modifications require FDA approval prior to marketing. Selenium is not approved for the free-choice formulations described in paragraph (e)(3)(iii) of this section. Free-choice cattle feeds containing selenium must comply with published regulations (*see* 21 CFR 573.920).

[2]The percentage of cane molasses and water in the formulation may be adjusted as needed in order to bring the brix value of the molasses to the industry standard of 79.5 brix.

(B) *Indications for use.* As in paragraph (e)(3)(i) of this section.

(C) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(4) *Horses.*

Amount fenbendazole in grams per ton	Indications for use	Limitations	Sponsor
(i) 4,540	5 mg/kg body weight (2.27 mg/lb) for the control of large strongyles (*Strongylus edentatus, S. equinus, S. vulgaris, Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), and pinworms (*Oxyuris equi*); 10 mg/kg body weight (4.54 mg/lb) for the control of ascarids (*Parascaris equorum*)..	Feed at the rate of 0. 1lb of feed per 100 lb of body weight to provide 2.27 mg fenbendazole/lb of body weight in a 1-day treatment or 0.2 lb of feed per 100 lb of body weight to provide 4.54 mg fenbendazole/lb of body weight in a 1-day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed. Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection. Do not use in horses intended for human consumption..	000061
(ii) [Reserved]			

(5) *Zoo and wildlife animals.*

Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) Feral swine (*Sus scrofa*).	3 mg/kg/day for 3 days..	For the removal and control of kidney worm (*Stephanurus dentatus*), roundworm (*Ascaris suum*), nodular worm (*Oesophagostomum dentatum*).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(ii) Ruminants (subfamily Antilopinae, Hippotraginae, Caprinae).	2.5 mg/kg/day for 3 days..	For the removal and control of small stomach worm (*Trichostrongylus* spp.), thread necked intestinal worm (*Nematodirus* spp.), barberpole worm (*Haemonchus* spp.), whipworm (*Trichuris* spp.).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061
(iii) Rocky mountain bighorn sheep (*Ovis c. canadensis*).	10 mg/kg/day for 3 days..	For the removal and control of *Protostrongylus* spp.	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	000061

[66 FR 58935, Nov. 26, 2001, as amended at 68 FR 34534, June 10, 2003; 72 FR 66046, Nov. 27, 2007; 73 FR 58873, Oct. 8, 2008; 74 FR 61517, Nov. 25, 2009]

§ 558.261 Florfenicol.

(a) *Specifications.* Type A medicated articles containing florfenicol in the following concentrations:

(1) 40 grams per kilogram for use as in paragraph (e)(1) of this section.

(2) 500 grams per kilogram for use as in paragraphs (e)(2) and (e)(3) of this section.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations*—(1) Federal law limits this drug to use under the professional supervision of a licensed

veterinarian. See § 558.6 of this chapter for additional requirements.

(2) The expiration date of veterinary feed directives (VFDs) for florfenicol medicated feeds:

(i) For catfish and freshwater-reared salmonids, must not exceed 15 days from the date of issuance;

(ii) For swine must not exceed 90 days from the date of issuance.

(3) VFDs for florfenicol shall not be refilled.

(d) *Related tolerances.* See § 556.283 of this chapter.

(e) *Conditions of use*—(1) *Swine*—

Florfenicol in grams/ton of feed	Indications for use	Limitations
182	For the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Streptococcus suis*, and *Bordetella bronchiseptica* in groups of swine in buildings experiencing an outbreak of SRD.	Feed continuously as a sole ration for 5 consecutive days. The safety of florfenicol on swine reproductive performance, pregnancy, and lactation have not been determined. Feeds containing florfenicol must be withdrawn 13 days prior to slaughter.

(2) *Fish*—

Florfenicol in grams/ton of feed	Indications for use	Limitations
(i) 182 to 1,816	Catfish: For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri.*	Feed as a sole ration for 10 consecutive days to deliver 10 milligrams florfenicol per kilogram of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be re-evaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 12 days prior to slaughter.

Florfenicol in grams/ton of feed	Indications for use	Limitations
(ii) 182 to 1,816	Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* and furunculosis associated with *Aeromonas salmonicida.*	Feed as a sole ration for 10 consecutive days to deliver 10 milligrams florfenicol per kilogram of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be re-evaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

[70 FR 70047, Nov. 21, 2005, as amended at 71 FR 70304, Dec. 4, 2006; 72 FR 19798, Apr. 20, 2007; 72 FR 65885, Nov. 26, 2007]

§ 558.265 Halofuginone hydrobromide.

(a) *Specifications.* Type A medicated articles containing 6 grams of halofuginone hydrobromide per kilogram.

(b) *Approvals.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.308 of this chapter.

(d) *Conditions of use.* (1) It is used in feed for broiler chickens as follows:

(i) *Amount.* 2.72 grams per ton.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima.*

(B) *Limitations.* Feed continuously as sole ration; withdraw 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bambermycins 1 to 2 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima;* for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers.

(iii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima;* for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(iv) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 to 15 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mevati*, *and E. maxima;* for increased rate of weight gain.

(B) *Limitations.* Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers.

(v) *Amount per ton.* Halofuginone hydrobromide 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams and roxarsone 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima;* for increased rate of weight gain; and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before slaughter; use as sole source of organic arsenic; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(vi) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mevati*, *E. maxima* and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 5 days before

slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(vii) *Amount per ton.* Halofuginone 2.72 grams (0.0003 percent) plus lincomycin 2 to 4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima* and for improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration; withdraw 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(viii) *Amount per ton.* Halofuginone hydrobromide, 2.72 grams plus roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Use as the sole source of organic arsenic; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens or waterfowl. Withdraw 5 days before slaughter.

(2) It is used in feed for turkeys as follows:

(i) *Amount per ton.* 1.36 to 2.72 grams.

(A) *Indications for use.* For the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis.*

(B) *Limitations.* Feed continuously as sole ration; withdraw 7 days before slaughter; do not feed to layers or water fowl; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) *Amount per ton.* Halofuginone hydrobromide 1.36 to 2.72 grams plus bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis.*, and *E. gallopavonis,* and for increased rate of weight gain in growing turkeys.

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or water fowl. Keep out of lakes, ponds, and streams. Halofuginone is toxic to fish and aquatic life. Halofuginone is an irritant to eyes and skin. Avoid contact with skin, eyes, or clothing.

(iii) *Amount per ton.* 1.36 to 2.72 grams of halofuginone hydrobromide plus 2 grams of bambermycins.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain in growing turkeys.

(B) *Limitations.* Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or waterfowl. Halofuginone hydrobromide is toxic to fish and other aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an eye and skin irritant. Avoid contact with skin, eyes, and clothing.

(3) It is used in feed for replacement cage laying chickens and replacement broiler breeder chickens as follows:

(i) *Amount per ton.* 2.72 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. mivati/E. mitis,* and *E. brunetti.*

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Withdraw 4 days before slaughter. Do not feed to laying chickens or water fowl. Halofuginone hydrobromide is toxic to fish and aquatic life. Keep out of lakes, ponds, and streams. Halofuginone hydrobromide is an irritant to eyes and skin. Avoid contact with skin, eyes, and clothing.

(ii) *Amount per ton.* Halofuginone hydrobromide, 2.72 grams plus roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*; for increased rate of weight gain, improved

feed efficiency, and improved pigmentation.

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Use as the sole source of organic arsenic; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens or waterfowl. Withdraw 5 days before slaughter.

[50 FR 33719, Aug. 21, 1985, as amended at 50 FR 42518, Oct. 21, 1985; 51 FR 7397, Mar. 3, 1986; 51 FR 11439, Apr. 3, 1986; 51 FR 14989, Apr. 22, 1986; 51 FR 23737, July 1, 1986; 53 FR 1018, Jan. 15, 1988; 53 FR 11065, Apr. 5, 1988; 54 FR 11519, Mar. 21, 1989; 54 FR 28052, July 5, 1989; 59 FR 51498, Oct. 12, 1994; 61 FR 21076, May 9, 1996; 61 FR 24694, May 16, 1996; 64 FR 42597, Aug. 5, 1999; 65 FR 45712, July 25, 2000; 66 FR 47962, Sept. 17, 2001; 71 FR 27956, May 15, 2006]

§ 558.274 Hygromycin B.

(a) *Approvals.* (1) Type A medicated articles: 2.4 and 8 grams per pound to 000986 in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(2) 2.4 grams per pound to No. 051311 in § 510.600(c) of this chapter for use in swine feed as in paragraph (c)(1)(ii) of this section.

(3) [Reserved]

(4) 0.6 gram per pound to 017790 and 043733 in § 510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) of this section and in swine as in paragraph (c)(1)(ii) of this section.

(5)–(7) [Reserved]

(8) 0.6 and 1.6 grams per pound granted to 046573 in § 510.600(c) of this chapter for use in chickens as in paragraph (c)(1)(i) and in swine as in paragraph (c)(1)(ii) of this section.

(b) *Related tolerances.* See § 556.330 of this chapter.

(c) *Conditions of use.* (1) It may be used as follows:

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 8 to 12	.....	Chickens: control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).	Withdraw 3 days before slaughter.	000986, 017790, 043733, 046573
	Bacitracin 100	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate or zinc bacitracin; withdraw 3 days before slaughter.	
	Bacitracin plus penicillin (100 to 200 of combination).	1. Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata);* treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	Feed containing not less than 25% of penicillin plus not less than 50% of bacitracin; as procaine penicillin plus bacitracin methylene disalicylate; withdraw 3 days before slaughter.	
		2. Chickens; control of infestation of large roundworms (*Ascaris galli),* cecal worms (*Heterakis gallinae),* and capillary worms (Capillaria obsignata); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	Combination containing not less than 50% nor more than 75% of bacitracin, except that it contains not more than 125 g of penicillin; as procaine penicillin plus zinc bacitracin; withdraw 3 days before slaughter.	
		3. Chickens, control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	Combination containing 50% to 75% bacitracin, but not more than 125 g of penicillin, as procaine penicillin; withdraw 3 days before slaughter..	

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Chlortetracycline 100 to 200.	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed for 7 to 14 days; withdraw 3 days before slaughter.	
	Chlortetracycline 200 to 400.	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*H. Gallinae*), and capillary worms (*Capillaria obsignata*); control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	.....do.	
	Penicillin 100	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (airsac infection), blue comb (nonspecific infectious enteritis).	As procaine penicillin; withdraw 3 days before slaughter.	
	Tylosin 4 to 50	Chickens: Control of infestations of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); growth promotion and feed efficiency.	As tylosin phosphate; withdraw 3 days before slaughter.	000986
(ii) 12	.....	Swine: control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*), and whipworms (*Trichuris suis*).	Withdraw 15 days before slaughter.	000986, 012286, 017790, 043733, 046573, 051311
	Chlortetracycline 400..	Swine; control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*) and whipworms (*Trichuris suis*); treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline..	Withdraw 15 d before slaughter..	
	Tylosin 10 to 100	Swine: Control of infestations of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*), and whipworms (*Trichuris suis*); growth promotion and feed efficiency.	As tylosin phosphate; withdraw 15 days prior to slaughter; feed continuously as follows:. Animal wt.(lbs.): Up to 40.....20 to 100[1] 41 to 100.....20 to 40[1] 101 to market wt.....10 to 20[1]	000986

[1] Amount of Tylosin (g/t).

(2) Hygromycin B may also be used in combination with:

(i) Amprolium in accordance with § 558.55.

(ii) Zoalene in accordance with § 558.680.

[41 FR 11000, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.274, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.295 Iodinated casein.

(a) *Approvals.* See 017762 in § 510.600(c) of this chapter.

(b) *NAS/NRC status.* The use of this drug is NAS/NRC reviewed and found effective. Applications for these uses

need not include efficacy data as required by § 514.111 of this chapter but may require bioequivalency or safety data.

(c) *Conditions of use*—(1) *Ducks*—(i) *Amount per ton*. 100 to 200 grams.

(ii) *Indications for use*. For increased rate of weight gain and improved feathering in growing ducks.

(2) *Dairy cows*—(i) *Amount per pound*. ½ to 1½ grams per 100 lb of body weight.

(ii) *Indications for use*. For increased milk production in dairy cows.

(iii) *Limitations*. This drug is effective for limited periods of time, and the effectiveness is limited to the declining phase of lactation. Administration must be accompanied with increased feed intake; administration may increase heat sensitivity of the animal.

[45 FR 41631, June 20, 1980]

§ 558.300 Ivermectin.

(a) *Specifications*. Type A medicated article containing 2.72 grams ivermectin per pound (g/lb).

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use in swine*. It is used in feed as follows:

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(1) 1.8 (to provide 0.1 milligram per kilogram (mg/kg) of body weight per day)		Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi*, adults and somatic larvae); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(2) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 10 to 30	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for increased rate of weight gain and improved feed efficiency.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(3) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 250	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where symptoms have not yet occurred, or following an approved treatment of disease condition.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(4) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 20	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*); and for increased rate of weight gain.	Feed as the only feed for 7 consecutive days. Not to be fed to swine that weigh more than 250 lbs. Withdraw 5 days before slaughter. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604
(5) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 40	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for control of swine dysentery on premises with a history of swine dysentery, but where symptoms have not yet occurred.	Feed as the only feed for 7 consecutive days. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter. Withdraw 5 days before slaughter. A separate feed containing 40 g/ton lincomycin may be continued to complete the lincomycin treatment.	050604
(6) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 100	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for treatment of swine dysentery.	Feed as the only feed for 7 consecutive days followed by a separate feed containing 100 g/ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604
(7) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 200	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for reduction in severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.	Feed as the only feed for 7 consecutive days followed by a separate feed containing 200 g/ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(8) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: For treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae); kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae); lungworms (*Metastrongylus* spp., adults); threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (*Haematopinus suis*); and mange mites (*Sarcoptes scabiei* var. *suis*).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(9) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 250	Pregnant sows: As in paragraph (e)(8) of this section; and for control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets.	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter. Feed bacitracin methylene disalicylate Type C medicated feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours.	050604
(10) 18.2 to 120 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: As in paragraph (e)(8) of this section.	Top dress on daily ration for individual treatment for 7 consecutive days. Withdraw 5 days before slaughter.	050604

[72 FR 37437, July 10, 2007]

§ 558.305 Laidlomycin.

(a) *Specifications.* Type A medicated articles containing 50 grams laidlomycin propionate potassium per pound.

(b) *Approvals.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.346 of this chapter.

(d) *Special considerations.* (1) Laidlomycin liquid Type B feeds may be manufactured from dry laidlomycin Type A articles. The liquid Type B feeds must have a pH of 6.0 to 8.0, dry matter of 62 to 75 percent, and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) The expiration date for the liquid Type B feed is 21 days after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 7 days after date of manufacture.

(3) Labeling for all Type B feeds (liquid and dry) and Type C feeds containing laidlomycin shall bear the following statements:

(i) Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium.

(ii) The safety of laidlomycin propionate potassium in unapproved species has not been established.

(iii) Not for use in animals intended for breeding.

(e) *Conditions of use*. It is used in cattle being fed in confinement for slaughter as follows:

Laidlomycin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 5	.....	For improved feed efficiency and increased rate of weight gain..	Feed continuously in a Type C feed at a rate of 30 to 75 mg/head/day..	046573
(2) 5	Chlortetracycline10 mg/lb body weight.	For improved feed efficiency and increased rate of weight gain; and for treatment of bacterial enteritis caused by *Echerichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	046573
(3) 5	Chlortetracycline 350 mg/head/day.	For improved feed efficiency and increased rate of weight gain; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	046573
(4) 5 to 10	.....	For improved feed efficiency.	Feed continuously in a Type C feed at a rate of 30 to 150 milligrams/head/day..	046573
(5) 5 to 10	Chlortetracycline 10 mg/pound body weight.	For improved feed efficiency; and for treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	046573
(6) 5 to 10	Chlortetracycline 350 mg/head/day.	For improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	046573

[59 FR 18297, Apr. 18, 1994, as amended at 60 FR 53509, Oct. 16, 1995; 62 FR 9929, Mar. 5, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 68 FR 13839, Mar. 21, 2003; 68 FR 42590, July 18, 2003; 69 FR 30198, May 27, 2004]

§ 558.311 Lasalocid.

(a) *Specifications*. A minimum of 90 percent of lasalocid activity is derived from lasalocid A.

(b) *Approvals*. Type A medicated articles approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (e) of this section as follows:

(1) 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20, and 50 percent activity to No. 046573 for use as in paragraphs (e)(1) (i), (ii), (iii), (iv), and (x) of this section.

(2) 15 percent activity to No. 066104 as provided by No. 046573 for use as in paragraph (e)(1)(v) of this section.

(3) 15, 20, 33.1, and 50 percent activity to No. 046573 for use in cattle feeds as in paragraphs (e)(1)(vi), (vii), (ix), (xi), (xii), and (xv) of this section, and for use in sheep as in paragraph (e)(1)(viii) of this section.

(4) 15 percent activity to No. 046573 for use in Type C rabbit feeds as in paragraph (e)(1)(xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2), (e)(3), and (e)(4) of this section.

(5) 15 and 20 percent activity to Nos. 012286 and 017800 for use in free-choice mineral feeds for cattle as in paragraph (e)(1)(xviii) of this section.

(6) 20 percent activity as a liquid Type A article to No. 046573 for use in cattle feeds as in paragraphs (e)(1)(vi), (e)(1)(vii), (e)(1)(ix), (e)(1)(xi), (e)(1)(xii), and (e)(3) of this section, and for use in sheep feeds as in paragraph (e)(1)(viii) of this section.

(7) 20 percent activity to No. 046573 for use as follows:

(i) Chukar partridges as in paragraph (e)(1)(xiii).

(ii) Turkeys as in paragraph (e)(1)(xiv).

(iii) Rabbits as in paragraph (e)(1)(xvi).

(8) [Reserved]

(9) 15 percent activity to No. 068287 for use in free-choice protein blocks for cattle as in paragraphs (e)(1)(xix) of this section.

(c) *Related tolerance.* See §556.347 of this chapter.

(d) *Special considerations.* (1) Type C cattle and sheep feeds may be manufactured from lasalocid liquid Type B feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable lasalocid liquid feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(3) If a manufacturer is unable to meet the requirements of paragraph (d)(1) or (d)(2) of this section, the manufacturer may secure approval of a positionally stable liquid feed by:

(i) Either filing a new animal drug application for the product or establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental new animal drug application to establish physical stability; and

(iii) Requesting the sponsor of an approved new animal drug application to file a supplement to provide for use of its lasalocid Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the supplemental new animal drug application will be approved. The approval will provide a basis for the individual liquid feed manufacturer to manufacture under a medicated feed license the liquid mediated feed described in the master file. A manufacturer who seeks to market a physically unstable lasalocid liquid feed with mixing directions different from the standard directions established in paragraph (d)(1) of this section may also follow this procedure.

(4) If adequate information is submitted to show that a particular liquid feed containing lasalocid is stable outside the pH of 4.0 to 8.0, the pH restriction described in paragraphs (d)(1) and (d)(2) of this section may be waived.

(5) Required label statements:

(i) For liquid Type B feed (cattle and sheep): Mix thoroughly with grain and/or roughage prior to feeding. Feeding undiluted, mixing errors, or inadequate mixing (recirculation or agitation) may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

(ii) For Type A articles or Type B feeds (cattle and sheep): Feeding undiluted or mixing errors may result in an excess lasalocid concentration which could be fatal to cattle and sheep. Do not allow horses or other equines access to Type A articles or Type B feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established.

(iii) For Type A articles, Type B or Type C feeds (cattle): A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(6) Lasalocid Type A medicated articles containing lasalocid dried fermentation residue are for use in cattle and sheep feed only.

(7) Each use in a free-choice Type C cattle feed as in paragraphs (e)(1)(xii) and (e)(1)(xviii) of this section must be the subject of an approved NADA or supplemental NADA as provided in § 510.455 of this chapter.

(e)(1) *Conditions of use.* It is used as follows:

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 68 (0.0075 pct) to 113 (0.0125 pct).	.....	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	For broiler or fryer chickens only; feed continuously as the sole ration.	046573
(ii) 68 (0.0075 pct) to 113 (0.0125 pct).	Roxarsone 45.4 (0.005 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima* and as an aid in the reduction of lesions due to *E. tenella.*	For broiler or fryer chickens only; feed continuously as the sole ration; as sole source of organic arsenic; withdraw 5 d before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter.	046573
	Roxarsone 45.4 plus bambermycins 1 (0.00011 pct).	For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* as an aid in the reduction of lesions due to *E. tenella;* and for increased rate of weight gain.	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bambermycins provided by No. 016592.	046573
	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter..	016592
	Roxarsone 45.4 plus lincomycin 2.0.	For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* as an aid in the reduction of lesions due to *E. tenella;* and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, lincomycin provided by No. 000009.	046573
	Roxarsone 45.4 plus bacitracin 10 to 25.	For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* as an aid in the reduction of lesions due to *E. tenella;* and for increased rate of weight gain.	For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	046573

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Roxarsone 45.4 plus bacitracin 10 or 30.	For prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati* and *E. maxima;* as an aid in the reduction of lesions due to *E. tenella;* and for increased rate of weight gain (10 grams per ton) or improved feed efficiency (30 grams per ton).	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bacitracin zinc provided by No. 000004.	046573
	Roxarsone 45.5 plus bacitracin methylene disalicylate 50.	Prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti; E. mivati,* and *E. maxima;* reduction of lesions due to *E. tenella;* prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other susceptible organisms.	Feed continuously as sole ration; as sole source of organic arsenic; withdraw 5 days before slaughter.	046573
(iii) 68 (0.0075 pct).	Lincomycin 2 (0.00022 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by *Eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; withdraw 5 d before slaughter; Type C feed must be used within 4 weeks of manufacture; as lincomycin hydrochloride monohydrate.	046573
(iv) 68 (0.0075 percent).	Bacitracin 10 to 50 ..	For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	For broiler or fryer chickens only; feed continuously as the sole ration; bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	046573
(v) 68 (0.0075 pct) to 113 (0.0125 pct).	Virginiamycin 20	For prevention of coccidiosis caused by *Eimeria tenella E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; do not feed to laying chickens; lasalocid sodium provided by No. 046573 in § 510.600(c) of this chapter.	046573
(vi) 10 (0.0011 pct) to 30 (0.0033 pct).	.....	Cattle; for improved feed efficiency	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573
	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency and reduction of incidence and severity of liver abscesses.	In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 100 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl ($C_8 - C_{18}$) trimethyl ammonium oxytetracycline.	046573
(vii) 25 (0.0027 pct) to 30 (0.0033 pct).	.....	Cattle; for improved feed efficiency and increased rate of weight gain.	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573
	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency, increased rate of weight gain, and reduction of incidence and severity of liver abscesses.	In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 250 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl ($C_8 - C_{18}$) trimethyl ammonium oxytetracycline.	046573

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(viii) 20 (0.0022 pct) to 30 (0.0033 pct).	.....	Sheep; for the prevention of coccidiosis caused by *Eimeria ovina, E. crandallis, E. ovinoidalis* (*E. ninakohlyakimovae*), *E. parva,* and *E. intricata*.	In Type C feeds; for sheep maintained in confinement; feed continuously in complete feed to provide not less than 15 mg nor more than 70 mg of lasalocid sodium activity per head per day depending on body weight.	046573
(ix)	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture; the drug must be contained in at least 1 pound of feed..	046573
(x) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin 4 to 50	Broiler chickens; for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* and for improved feed efficiency.	For broiler chickens only; feed continuously as the sole ration; bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	046573
(xi) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin zinc 4 to 50.	Broiler chickens. For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bacitracin zinc and lasalocid sodium as provided by No. 046573 in § 510.600(c) of this chapter..	046573
(xii)	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day..	046573
(xiii)	.....	Cattle; for control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.	For cattle; hand feed at a rate of 1 mg of lasalocid per 2.2 pounds body weight per day to cattle weighing up to 800 pounds with a maximum of 360 mg of lasalocid per head per day.	046573
(xiv) 113 (0.0125 pct).	.....	Chukar partridges; for prevention of coccidiosis caused by *Eimeria legionensis.*	Feed continuously as sole ration up to 8 weeks of age.	046573
(xv) 68 (0.0075 pct) to 113 (0.0125 pct).	.....	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides*..	Feed continuously as sole ration.	046573
.....	Bacitracin 4 to 50	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides*; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration.	046573
.....	Bacitracin methylene disalicylate 4 to 50.	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides*; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter..	046573
.....	Roxarsone 22.7 to 45.4.	Growing turkeys: For prevention of coccidiosis caused by *E. meleagrimitis*, *E. gallopavonis*, and *E. adenoeides*, increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed continuously as the sole ration. Roxarsone provided by No. 046573 in § 510.600(c) in this chapter..	046573

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
.....	Virginiamycin 10 to 20.	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis, E. gallopavonis,* and *E. adenoeides,* and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. As lasalocid sodium provided by 063238 and virginiamycin provided by 066104..	046573
(xvi)	.....	Replacement calves; for control of coccidiosis caused by *E. bovis* and *E. zuernii*..	In milk replacer powder; hand feed at a rate of 1 mg of lasalocid per 2.2 lb body weight per day; include on labeling warning: "A withdrawal period has not been established for lasalocid in pre-ruminating calves. Do not use in calves to be processed for veal".	046573
(xvii) 113 (0.0125 pct).	.....	Rabbits; for prevention of coccidiosis caused by *Eimeria stiedae*.	Feed continuously as sole ration up to 6 1/2 weeks of age.	046573
(xviii) 1440	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain..	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day..	021930 017800
(xix) 300	.....	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain..	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day..	068287
(xx) 10 to 30	Chlortetracycline 25 to 100.	1. Cattle fed in confinement for slaughter: For improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline..	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day..	046573
.....	.....	2. Cattle under 700 pounds fed in confinement for slaughter: For improved feed efficiency; and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline..	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day..	046573
(xxi) 10 to 30	Chlortetracycline 500 to 2000.	Cattle fed in confinement for slaughter: For improved feed efficiency; and for treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline..	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day..	046573
(xxii) 25 to 30	Chlortetracycline 25 to 42.2.	1. Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline..	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day..	046573
.....	.....	2. Cattle under 700 pounds fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline..	Feed continuously in complete feed at a rate of 350 mg chlortetracycline and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day..	046573

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xxiii) 25 to 30	Chlortetracycline 500 to 1200.	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency; and for treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline..	Feed continuously in complete feed for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day..	046573
(xxiv) 30 to 181.8	Chlortetracycline 25 to 2800.	1. Beef cattle under 700 pounds: For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline..	Hand feed continuously at a rate of 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day..	046573
.....	.....	2. Beef cattle up to 800 pounds: For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline..	Hand feed continuously at a rate of 350 mg chlortetracycline per head per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day..	046573
(xxv) 30 to 181.8	Chlortetracycline 500 to 4000.	Cattle up to 800 pounds: For control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline..	Hand feed continuously for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and 1 mg lasalocid per 2.2 lb body weight per day with a maximum of 360 mg lasalocid per head per day..	046573
(xxvi) 30 to 600 ..	Chlortetracycline 25 to 700.	1. Pasture cattle (slaughter, stocker, feeder cattle, and beef replacement heifers): for increased rate of weight gain; and for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline..	Hand feed continuously at a rate of 350 mg chlortetracycline and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	046573
.....	.....	2. Pasture cattle under 700 pounds (slaughter, stocker, feeder cattle, and beef replacement heifers): for increased rate of weight gain; and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline..	Hand feed continuously at a rate of 350 mg chlortetracycline and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	046573
(xxvii) 30 to 600 ..	Chlortetracycline 25 to 1100.	Pasture cattle over 700 pounds (slaughter, stocker, feeder cattle, and beef replacement heifers): For increased rate of weight gain; and for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline..	Hand feed continuously at a rate of 0.5 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	046573

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xxviii) 30 to 600.	Chlortetracycline 500 to 4000..	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain; and for treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline..	Hand feed continuously for not more than 5 days to provide 10 mg chlortetracycline per lb body weight per day and not less than 60 mg or more than 300 mg lasalocid per head daily in at least 1 lb of feed. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	046573

(2) It is used as a free-choice mineral Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Defluorinated phosphate (20.5% Ca, 18.5% P)	35.9	6–01–080
Sodium chloride (salt)	20.0	6–04–152
Calcium carbonate (38% Ca)	18.0	6–01–069
Cottonseed meal	10.0	5–01–621
Potassium chloride	3.0	6–03–755
Selenium premix (0.02 percent Se)[1]	3.0	
Dried cane molasses (46% sugars)	2.5	4–04–695
Magnesium sulfate	1.7	6–02–758
Vitamin premix[1]	1.4	
Magnesium oxide (58% Mg)	1.2	6–02–756
Potassium sulfate	1.2	6–06–098
Trace mineral premix[1]	1.04	
Lasalocid Type A medicated article (68 g/lb)[2]	1.06	

[1] Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 1,440 g lasalocid per ton, use 21.2 lbs (1.06%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 15.88 lbs per ton (0.794%), adding molasses.

(ii) *Amount.* 1,440 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers); feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.

(v) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(3) It is used as a ruminant free-choice liquid Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Cane molasses	55.167	4–13–241
Condensed molasses fermentation solubles	24.0	
50% Urea Solution (23% N)	12.0	
Ammonium polyphosphate solution	1.0	6–08–42
Phosphoric acid (54%)	3.0	6–03–707
Xanthan gum	0.05	8–15–818
Water	4.0	
Trace mineral premix[1]	0.5	
Vitamin premix[1]	0.2	
Lasalocid Type A medicated article (90.7 g/lb)[2]	0.083	

[1] Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of a lasalocid liquid Type A medicated article containing 90.7 g/lb. If using a dry lasalocid Type A medicated article containing 68 g/lb, use, use 2.206 lbs per ton (0.111%), replacing molasses. If using a dry lasalocid Type A medicated article containing 90.7 g/lb, use 1.652 lbs per ton (0.083%), adding molasses.

(ii) *Amount.* 150 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.

(v) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(4) It is used as a free-choice, loose mineral Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% P)	57.70	6–01–082
Salt	17.55	6–04–152
Distillers dried grains w/ solubles	5.40	5–28–236
Dried cane molasses (46% Sugars)	5.20	4–04–695
Potassium chloride	4.90	6–03–755
Trace mineral/vitamin premix[1]	3.35	
Calcium carbonate (38% Ca)	2.95	6–01–069
Mineral oil	1.05	8–03–123
Magnesium oxide (58% Mg)	1.00	6–02–756
Iron oxide (52% Fe)	0.10	6–02–431
Lasalocid Type A medicated article (68 g/lb)[2]	0.80	

[1] Content of the vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 1,088 g lasalocid per ton, use 16 lbs (0.80%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 12 lbs per ton (0.6%), adding molasses.

(ii) *Amount.* 1,088 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* Feed continuously on a free-choice basis at a rate of 60 to 300 mg lasalocid per head per day.

(v) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(5) *Additional combinations.* Lasalocid may be used in accordance with the provisions of this section in combination as follows:

(i) Melengestrol acetate alone or in combination with tylosin in accordance with § 558.342.

(ii) [Reserved]

[41 FR 44382, Oct. 8, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.311, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

§ 558.325 Lincomycin.

(a) *Approvals.* Type A articles and Type B feeds approved for sponsors in § 510.600(c) of this chapter for specific uses as in paragraph (d) of this section as follows:

(1) No. 000009 for 20 and 50 grams per pound.

(2) No. 051311 for 2.5 and 8 grams per pound.

(b) *Related tolerances.* See § 556.360 of this chapter.

(c) *Special considerations*—(1) Labeling of Type A medicated articles and Type B and Type C medicated feeds containing lincomycin shall bear the following directions: ''CAUTION: Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.''

(2) Labeling of Type A medicated articles and Type B and Type C medicated feeds containing lincomycin intended for use in swine shall bear the

following directions: ''CAUTION: Occasionally, swine fed lincomycin may within the first 2 days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within 5 to 8 days without discontinuing the lincomycin treatment.''

(3) Labeling of Type A medicated articles and single-ingredient Type B and Type C medicated feeds containing lincomycin intended for use in swine shall bear the following directions:

(i) No. 000009: ''CAUTION: The effects of lincomycin on swine reproductive performance, pregnancy, and lactation have not been determined. Not for use in swine intended for breeding when lincomycin is fed at 20 grams per ton of complete feed.''

(ii) No. 051311:''CAUTION: Not to be fed to swine that weigh more than 250 lb.''

(d) *Conditions of use*—(1) *Chickens.* It is used in feed as follows:

Lincomycin grams/ton	Indications for use	Limitations	Sponsor
(i) 2	Broilers: For control of necrotic enteritis caused by *Clostridium* spp. or other susceptible organisms..	As lincomycin hydrochloride monohydrate.	000009
(ii) 2 to 4	Broilers: For increased rate of weight gain and improved feed efficiency..	As lincomycin hydrochloride monohydrate.	000009

(2) *Swine.* It is used in feed as follows:

Lincomycin grams/ton	Indications for use	Limitations	Sponsor
(i) 20	Growing-finishing swine: For increased rate of weight gain..	Feed as sole ration.	000009
(ii) 40	1. For control of swine dysentery.	Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred, or following use of lincomycin at 100 grams (g)/ton for treatment of swine dysentery..	000009 051311
	2. For control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*..	Feed as sole ration, or following use of lincomycin at 100 g/ton for control of porcine proliferative enteropathies (ileitis)..	000009
(iii) 100	1. For treatment of swine dysentery.	Feed as sole ration for 3 weeks or until signs of disease disappear..	000009 051311
	2. For control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*..	Feed as sole ration for 3 weeks or until signs of disease disappear..	000009
(iv) 200	For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*..	Feed as sole ration for 3 weeks.	000009 051311

(3) Lincomycin may also be used in combination with:

(i) Amprolium and ethopabate or amprolium and ethopabate with roxarsone in accordance with § 558.58.

(ii) Clopidol in accordance with § 558.175.

(iii) Decoquinate in accordance with § 558.195.

(iv) Fenbendazole as provided in § 558.258.

(v) Halofuginone in accordance with § 558.265.

(vi) Ivermectin as in § 558.300.

(vii) Lasalocid alone or with roxarsone in accordance with § 558.311.

(viii) Monensin alone or with roxarsone in accordance with § 558.355.

(ix) Nicarbazin alone or with narasin or roxarsone as in § 558.366.

(x) Pyrantel as in § 558.485.

(xi) Robenidine in accordance with § 558.515.

(xii) Roxarsone in accordance with § 558.530.

(xiii) Salinomycin with or without roxarsone as in § 558.550.

(xiv) Zoalene in accordance with § 558.680.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.325, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.340 Maduramicin ammonium.

(a) *Approvals*. Type A medicated articles: 4.54 grams per pound to 046573 in § 510.600(c) of this chapter.

(b) *Tolerances*. See § 556.375 of this chapter.

(c) *Conditions of use*—(1) *Amount*. 4.54 to 5.45 grams per ton (5 to 6 parts per million) (1 to 1.2 pounds per ton).

(i) *Indications for use*. For prevention of coccidiosis caused by *Eimeria acervulina, E. tenella, E. brunetti, E. maxima, E. necatrix, and E. mivati*.

(ii) *Limitations*. For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter.

(2) [Reserved]

[54 FR 5229, Feb. 2, 1989, as amended at 54 FR 26732, June 26, 1989; 54 FR 32635, Aug. 9, 1989; 54 FR 33885, Aug. 17, 1989; 55 FR 23, Jan. 2, 1990; 55 FR 8460, Mar. 8, 1990; 55 FR 49616, Nov. 30, 1990; 59 FR 8134, Feb. 18, 1994; 61 FR 18082, Apr. 24, 1996; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001]

§ 558.342 Melengestrol.

(a) *Specifications*. (1) Dry Type A medicated articles containing 100 or 200 milligrams (mg) melengestrol acetate per pound.

(2) Liquid Type A medicated article containing 500 mg melengestrol acetate per pound.

(b) *Approvals*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000009 for use of products described in paragraph (a) of this section.

(2) No. 021641 for use of product described in paragraph (a)(2) of this section.

(c) *Related tolerances*. See § 556.380 of this chapter.

(d) *Special considerations*. (1) Type B or C medicated feeds may be manufactured from melengestrol acetate liquid Type A articles or Type B or C medicated feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable melengestrol acetate liquid Type B or C feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not less than 300 centipoises per second for 3 months.

(3) Combination Type B or C medicated feeds containing lasalocid must be labeled in accordance with § 558.311(d)(5) of this chapter.

(4) Liquid combination Type B or C medicated feeds containing melengestrol acetate and lasalocid must be manufactured in accordance with § 558.311(d) of this chapter.

(5) Combination Type B or C medicated feeds containing monensin must be labeled in accordance with § 558.355(d) of this chapter.

(6) Liquid combination Type B or C medicated feeds containing melengestrol acetate and monensin must be manufactured in accordance with § 558.355(f)(3)(i) of this chapter.

(7) Liquid combination Type B or C medicated feeds containing melengestrol acetate and tylosin must be manufactured in accordance with § 558.625(c) of this chapter.

(8) Liquid melengestrol acetate may not be mixed with oxytetracycline in a common liquid feed supplement.

(e) *Conditions of use*—(1) *Cattle*.

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(i) 0.25 to 0.5	.....	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)..	Administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day..	000009, 021641
(ii) 0.5	.....	Heifers intended for breeding: For suppression of estrus (heat)..	Administer 0.5 to 2.0 lb/head/day of Type C feed containing 0.25 to 1.0 mg melengestrol acetate/lb to provide 0.5 mg melengestrol acetate/head/day. Do not exceed 24 days of feeding..	000009, 021641
(iii) 0.25 to 0.5	Lasalocid 100 to 360	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section..	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 30 grams (g) of lasalocid per ton; or add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate plus 50 to 720 mg lasalocid/lb to a ration of nonmedicated feed to provide 0.25 to 0.5 mg melengestrol acetate and 100 to 360 mg lasalocid/head/day. . Lasalocid provided by No. 046573 in § 510.600(c) of this chapter..	000009, 021641
(iv) 0.25 to 0.5	Lasalocid 100 to 360 plus tylosin 90..	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduced incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*..	To administer 0.25 to 0.5 mg melengestrol acetate plus 100 to 360 mg lasalocid plus 90 mg tylosin/head/day:. 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 10 to 30 g lasalocid and 8 to 10 g tylosin per ton; or. 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 50 to 720 mg lasalocid/lb to 4.5 to 18 lb of a dry medicated feed containing 10 to 40 g tylosin per ton; or. 3. Add 0.5 to 2.0 lb/head/day of a dry pelleted medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article), 50 to 720 mg lasalocid, and 45 to 180 mg tylosin/lb to a ration of nonmedicated feed.. Lasalocid provided by No. 046573 and tylosin as tylosin phosphate by No. 000986 in § 510.600(c) of this chapter.. 021641.	
(v) [Reserved]. (vi)–(vii) [Reserved].				

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(viii) 0.25 to 0.5 ..	Oxytetracycline 75 ...	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduction of liver condemnation due to liver abscesses..	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb per pound to a feed containing 6 to 10 g oxytetracycline per ton; or add at the rate of 0.5 to 2.0 lb/head/day a dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate plus 37.5 to 150 mg oxytetracycline/lb to provide 0.25 to 0.5 mg melengestrol acetate and 75 mg oxytetracycline/head/day.. Oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter..	000009
(ix) 0.25 to 0.5	Tylosin 60 to 90	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for reduced incidence of liver abscesses caused by *F. necrophorum* and *Actinomyces* (*Corynebacterium*) *pyogenes*..	To administer 0.25 to 0.5 mg melengestrol acetate with 60 to 90 mg tylosin/head/day:. 1. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to a medicated feed containing 8 to 10 g tylosin per ton; or. 2. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to 4.5 to 18 pounds of a dry medicated feed containing 10 to 40 g tylosin per ton; or. 3. Add 0.5 to 2.0 lb/head/day of a liquid or dry medicated feed containing 0.125 to 1.0 mg melengestrol acetate (from a dry Type A article) plus 45 to 180 mg tylosin/lb to a ration of nonmedicated feed.. Tylosin as tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter..	000009, 021641
(x) 0.25 to 0.5	Monensin 50 to 480.	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*..	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 40 g of monensin per ton to provide 0.25 to 0.5 mg melengestrol acetate/head/day and 0.14 to 0.42 mg monensin/lb body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day.. ..... Monensin provided by No. 000986 in § 510.600(c) of this chapter..	000009

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
(xi) 0.25 to 0.5	Monensin 50 to 480, plus tylosin 60 to 90.	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*..	Feed continuously as sole ration (liquid or dry) at a rate of 0.5 to 2.0 lb/head/day to provide 0.25 to 0.5 mg/head/day melengestrol acetate; 0.14 to 0.42 mg monensin/lb body weight/day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day; and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into a complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin in the amount of complete feed consumed by an animal per day.. ..... Monensin and tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter..	000009 02164

(2) Melengestrol may also be used with:

(i) Ractopamine as in § 558.500 of this chapter.

(ii) Zilpaterol as in § 558.665 of this chapter.

[42 FR 28535, June 3, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations effecting § 558.342, see the List of CFR Section Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.348 Mibolerone.

(a) *Approvals.* To No. 000009 in § 510.600(c) of this chapter for a canned dog food, each 6½ ounce can containing 30 or 60 micrograms of mibolerone.

(b) *Conditions of use*—(1) *Amount.* 30 micrograms for animals weighing up to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, or German Shepherds or German Shepherd mix weighing 30 to 80 pounds.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations.* Administer daily at least 30 days before expected initiation of heat and continue as long as desired, but for not more than 12 months. Mibolerone should not be used in bitches before first estrous period or in purebred Bedlington terriers. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 6617, Feb. 16, 1982]

§ 558.355 Monensin.

(a) *Specifications.* Type A medicated articles containing monensin, USP.

(b) *Approvals.* Approvals for Type A medicated articles containing the specified levels of monensin activity granted to firms identified by sponsor numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section are as follows:

(1) To No. 000986: 36.3 (for export only), 44, 45, 60, or 90.7 grams per pound for use as in paragraphs (f)(1)(i) and (f)(4) of this section.

(2) To 000986: 110 grams per lb., paragraphs (f)(1) (i), (iii), (iv), (v), (ix), and (x).

(3) To 000986: 44 grams per lb. with 18 grams per lb. of roxarsone, 110 grams per lb. with 45 grams per lb. of roxarsone, paragraph (f)(1)(ii).

(4) To No. 000986: 45, 60, or 90.7 grams per pound for use as in paragraph (f)(2) of this section.

(5) To 066104: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xiii), (xx), and (xxi) of this section.

(6) To No. 000986: 45, 60, or 90.7 grams per pound for use as in paragraph (f)(5) of this section.

(7) To 000986: 20, 30, 45, 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(3) of this section.

(8) To 046573: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xiv) of this section.

(9) To 046573: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xv) and (xvi) of this section.

(10) To 016592: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(1)(xvii) of this section.

(11) To 046573: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xiv), (xviii), (xix), (xxiii), (xxiv), (xxv), (xxvi), and (xxvii) of this section.

(12) To 066104: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xxii) of this section.

(13) To No. 012286: 60 and 80 grams per pound, paragraph (f)(3)(v) of this section.

(14) To 000986: 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(6) of this section.

(c) [Reserved]

(d) *Special considerations.* (1) Type C chicken feed containing monensin as the mycelial cake shall bear an expiration date of 90 days after its date of manufacture.

(2)—(3) [Reserved]

(4) Liquid Type B feeds shall bear an expiration date of 8 weeks after its date of manufacture.

(5) All Type A medicated articles containing monensin shall bear the following warning statement: When mixing and handling monensin Type A medicated articles, use protective clothing, impervious gloves, and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water.

(6) All formulations containing monensin shall bear the following caution statement: Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal.

(7) Type A medicated articles containing monensin intended for use in cattle and goats shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following statements:

(i) Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions.

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats.

(iii) Must be thoroughly mixed in feeds before use.

(iv) Do not feed undiluted.

(v) Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

(vi) Do not feed to lactating goats.

(vii) If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing.

(viii) A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(ix) You may notice the following: Reduced voluntary feed intake in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Rule out monensin as the cause of reduced feed intake before attributing to other causes such as illness, feed management, or the environment. Reduced milk fat percentage in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Increased incidence of cystic ovaries and metritis in dairy cows fed monensin. Reduced conception rates, increased services per animal, and extended days open and corresponding calving intervals in dairy cows fed monensin. Have a comprehensive and

ongoing nutritional, reproductive, and herd health program in place when feeding monensin to dairy cows.

(x) Inadequate mixing (recirculation or agitation) of monensin liquid Type B or Type C medicated feeds has resulted in increased monensin concentration which has been fatal to cattle and could be fatal to goats.

(8) Type A medicated articles containing monensin intended for use in chickens, turkeys, and quail shall bear the following statements:

(i) Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal.

(ii) Must be thoroughly mixed in feeds before use.

(iii) Do not feed undiluted.

(iv) Do not feed to laying chickens.

(v) Do not feed to chickens over 16 weeks of age.

(vi) For replacement chickens intended for use as cage layers only.

(vii) Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(viii) In the absence of coccidiosis in broiler chickens the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain.

(9) Type B feeds containing monensin shall bear the statements specified in the following paragraphs of this section when intended for use in:

(i) *Cattle (as described in paragraphs (f)(3)(i) through (f)(3)(xii) of this section)*: See paragraphs (d)(6), (d)(7)(i) through (d)(7)(v), (d)(7)(vii), and (d)(7)(viii) of this section.

(ii) *Dairy cows (as described in paragraphs (f)(3)(xiii) and (f)(3)(xiv) of this section)*: See paragraphs (d)(6), (d)(7)(i) through (d)(7)(iv), (d)(7)(vii), (d)(7)(viii), and (d)(7)(ix) of this section.

(iii) *Goats*: See paragraphs (d)(6) and (d)(7)(i) through (d)(7)(vi) of this section.

(iv) *Chickens*: See paragraphs (d)(8)(i) through (d)(8)(vi), and (d)(8)(viii) of this section.

(v) *Turkeys:* See paragraphs (d)(8)(i), (d)(8)(ii), (d)(8)(iii), and (d)(8)(vii) of this section.

(vi) *Quail*: See paragraphs (d)(8)(i), (d)(8)(ii), and (d)(8)(iii) of this section.

(10) Type C feeds containing monensin shall bear the statements specified in the following paragraphs of this section when intended for use in:

(i) *Cattle (as described in paragraphs (f)(3)(i) through (f)(3)(xii) of this section)*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(v), (d)(7)(vii), and (d)(7)(viii) of this section.

(ii) *Dairy cows (as described in paragraphs (f)(3)(xiii) and (f)(3)(xiv) of this section)*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(vii), (d)(7)(viii), and (d)(7)(ix) of this section.

(iii) *Goats*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(v), and (d)(7)(vi) of this section.

(iv) *Chickens*: See paragraphs (d)(8)(i), (d)(8)(iv), (d)(8)(v), (d)(8)(vi), and (d)(8)(viii) of this section.

(v) *Turkeys*: See paragraphs (d)(8)(i) and (d)(8)(vii) of this section.

(vi) *Quail*: See paragraph (d)(8)(i) of this section.

(11) Type B and Type C liquid feeds requiring recirculation or agitation that contain monensin and are intended for use in cattle (including dairy cows) and goats shall bear the caution statement specified in paragraph (d)(7)(x) of this section.

(12) Mixing directions for liquid feeds requiring recirculation or agitation:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *Related tolerances*. See § 556.420 of this chapter.

(f) *Conditions of use*. It is used as follows:

(1) *Broiler chickens*—(i) *Amount per ton*. Monensin, 90–110 grams.

(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by

E. necatrix, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 480 milligrams of monensin and 60 to 90 milligrams of tylosin per head per day. Combination drug liquid Type B medicated feeds may be used to manufacture dry Type C medicated feeds as in § 558.625(c) of this chapter.

(ii) *Amount per ton.* Monensin, 90–110 grams, plus roxarsone 45.4 grams (0.005 percent).

(*a*) *Indications for use.* Growth promotion and feed efficiency, improving pigmentation; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati* and *E. maxima*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin or monensin sodium.

(iii) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 5–25 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium.

(iv) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium.

(v) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10–30 grams.

(*a*) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium.

(vi) *Amount per ton.* Monensin, 90 to 110 grams; plus bambermycins, 1 to 2 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; and as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*,*E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Monensin, 90 to 110 grams; plus bambermycins, 1 gram; plus roxarsone, 22.7 to 45.4 grams

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; and as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Feed continuously as sole ration; use as sole source of organic arsenic; withdraw 5 d before slaughter; do not feed to laying chickens. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter; roxarsone provided by No. 046573.

(viii) *Amount per ton.* Monensin, 90 to 110 grams plus oxytetracycline, 200 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima;* and for the control of complicated chronic respiratory disease (CRD or air-sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli*.

(*b*) *Limitations.* In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; do not feed to laying chickens; feed continuously as sole ration; as monensin sodium.

(ix) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; to be fed as a sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as monensin sodium.

(x) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams and roxarsone, 15–45 grams.

(*a*) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573, §510.600(c) of this chapter; as monensin sodium provided by No. 000986, §510.600(c) of this chapter; as lincomycin provided by No. 000009, §510.600(c) of this chapter; as a combination provided by No. 000009, §510.600(c) of this chapter.

(xi) *Amount per ton.* Monensin, 90 to 110 grams, plus lincomycin, 2 grams and roxarsone, 15 to 30 grams.

(*a*) *Indications for use.* For increase in rate of weight gain, improved feed efficiency, improved pigmentation, and as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573 in §510.600(c) of this chapter; as monensin sodium provided by No. 000986 in §510.600(c) of this chapter; as lincomycin provided by No. 000009 in §510.600(c) of this chapter; as a combination provided by No. 000009 in §510.600(c) of this chapter.

(xii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 10 to 25 grams, and roxarsone, 11.3 to 45.4 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. maxima*, and *E. mivati;* for increased rate of weight gain and for improved feed efficiency.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in §510.600 of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in §510.600 of this chapter; as roxarsone provided by No. 011526 or 046573 in §510.600 of this chapter.

(xiii) *Amount per ton.* Monensin, 90 to 110 grams, plus 5 grams virginiamycin.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. maxima*, and *E. mivati;* for increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in §510.600 of this chapter; virginiamycin provided by No. 066104 in §510.600 of this chapter.

(xiv) *Amount per ton.* Monensin, 90 to 110 grams, plus 500 grams chlortetracycline.

(*a*) *Indications for use.* As an aid in the reduction of mortality due to *Escherichia coli* infections susceptible to such treatment. As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed for 5 days as the sole ration; withdraw 24 hours before slaughter; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; not to be fed continuously for more than 5 days; as monensin sodium; as chlortetracycline

hydrochloride provided by Nos. 046573 and 048164 in § 510.600(c) of this chapter.

(xv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 10 grams, and roxarsone, 15 grams (0.0017 percent).

(*a*) *Indications for use.* For increase in rate of weight gain; for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xvi) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams, and roxarsone, 15 to 45.4 grams (0.0017 percent to 0.005 percent).

(*a*) *Indications for use.* For improved feed efficiency; for improved pigmentation by enhancing carotenoid and xanthophyll utilization; for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xvii) *Amount per ton.* Bambermycins, 1 to 2 grams plus monensin, 90 to 110 grams plus roxarsone, 22.7 to 45.4 grams.

(*a*) *Indications for use.* For increased rate of weight gain; and as an aid in prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Feed continuously as sole ration; use as sole source of organic arsenic; withdraw 5 d before slaughter; do not feed to laying chickens. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter; roxarsone provided by No. 046573.

(xviii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 34.0 grams (0.0025 percent to .00375 percent).

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium spp* or other organisms susceptible to bacitracin methylene disalicylate.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xix) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to .005 percent).

(*a*) *Indications for use.* For increased rate of weight gain; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium spp* or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xx) *Amount per ton.* Monensin, 90 to 110 grams, plus virginiamycin, 5 to 15 grams, and roxarsone, 22.7 grams (0.0025 percent).

(*a*) *Indications for use.* For incease in rate of weight gain; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E.*

acervulina, *E. maxima*, *E. brunetti*, and *E. mivati*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as virginiamycin provided by No. 066104 in § 510.600(c) of this chapter; roxarsone provided by Nos. 046753 and 011526 in § 510.600(c) of this chapter.

(xxi) *Amount per ton.* Monensin, 90 to 110 grams, plus virginiamycin, 5 to 15 grams.

(*a*) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in § 510.600 of this chapter; virginiamycin provided by No. 066104 in § 510.600 of this chapter.

(xxii) *Amount per ton.* Monensin, 90 to 110 grams plus oxytetracycline, 500 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. Mivati*, and *E. maxima;* as an aid in the reduction of mortality due to air-sacculities (air-sac infection) caused by *Escherichia coli* sensitive to oxytetracycline.

(*b*) *Limitations.* Feed for 5 days as sole ration. Do not feed to laying chickens. Withdraw 24 hours before slaughter. As monensin sodium provided by No. 000986 in § 510.600(c) of this chapter. As mono-alkyl (C_8-C_{18}) trimethylammonium oxytetracycline provided by No. 066104 in § 510.600(c) of this chapter.

(xxiii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to 0.005 percent).

(*a*) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xxiv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 4 to 50 grams.

(xxv) *Amount per ton.* Monensin, 90 to 110 grams plus bacitracin, 4 to 50 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter, as monensin sodium.

(xxvi) *Amount per ton.* Monensin 90 to 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 34.0 grams.

(*a*) *Indications for use.* As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; for increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at first clinical signs of disease. The dosage range permitted provides for different levels based on the severity of infection. Use continuously for 5 to 7 days or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

(xxvii) *Amount per ton.* Monensin 90 to 110 grams plus bacitracin 100 to 200 grams and roxarsone 22.7 to 45.4 grams.

(*a*) *Indications for use.* As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; for increased rate of weight gain.

(*b*) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying hens. To control necrotic enteritis, start medication at first clinical signs of disease. The dosage range permitted provides for different levels based on the severity of infection. Use continuously for 5 to 7 days or as long as clinical signs persist, then reduce dosage to prevention level. Animals should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness. As roxarsone and bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

(xxviii) *Amount per ton.* Monensin, 90 to 110 grams, plus tylosin phosphate, 4 to 50 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, for increased rate of weight gain, and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens. As monensin sodium and tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter.

(xxix) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 50 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(xxx) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 100 to 200 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium spp.* or other organisms susceptible to bacitracin.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(2) *Turkeys*—(i) *Amount per ton.* Monensin, 54 to 90 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*.

(*b*) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(ii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 4 to 50 grams.

(*a*) *Indications for use.* For prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*, for increased rate of

weight gain, and for improved feed efficiency.

(*b*) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 200 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides, E. meleagrimitis,* and *E. gallopavonis,* and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(*b*) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

(iv) *Amount per ton.* Monensin, 54 to 90 grams, with virginiamycin, 10 to 20 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(*b*) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses, mature turkeys, and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.

(v) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 1 to 2 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for improved feed efficiency in growing turkeys.

(*b*) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 2 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(*b*) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.

(3) *Cattle*—(i) *Amount per ton.* Monensin, 5–40 grams.

(*a*) *Indications for use.* Improved feed efficiency.

(*b*) *Limitations.* (*1*) Feed only to cattle being fed in confinement for slaughter. Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 milligrams per head per day). Complete feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions as defined in paragraph (d)(12) of this section. The liquid feed must bear caution statement as follows: Inadequate mixing, (recirculation or agitation), of liquid feeds has

resulted in increased monensin concentration which has been fatal to cattle.

(*2*) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)(12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(*i*) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(*ii*) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(*iii*) Requesting No. 000986 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

(ii) *Amount per ton.* Monensin, 5 to 40 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use.* Cattle fed in confinement for slaughter: For improved feed efficiency; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes.*

(*b*) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 480 milligrams of monensin and 60 to 90 milligrams of tylosin per head per day. Combination drug liquid Type B medicated feeds may be used to manufacture dry Type C medicated feeds and shall conform to mixing instructions as in 558.625(c) of this chapter.

(iii) *Amount per ton.* Monensin, 25 to 400 grams.

(*a*) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*

(*b*) *Limitations.* For increased rate of weight gain, feed at a rate of 50 to 200 milligrams monensin per head per day in not less than 1 pound of feed or, after the 5th day, feed at a rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending on severity of challenge, up to 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per day in not less than 1 pound of feed.

(iv) *Amount.* Monensin at concentrations in free-choice Type C medicated feeds to provide 50 to 200 mg per head per day.

(*a*) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*

(*b*) *Limitations.* During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated supplement before using the monensin medicated supplement. The product's effectiveness in cull cows and bulls has not been established. See paragraph (d) of this section for other required label warnings.

(v) *Amount.* 150 milligrams per pound (0.033 percent).

(*a*) *Indications for use.* For increased rate of weight gain and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii.*

(*b*) *Limitations.* As protein-mineral blocks to be fed free choice to cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) on pasture which may require supplemental feed. Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). Block's effectiveness in cull cows and bulls has not been established. Approval must comply with § 510.455 of this chapter.

(vi) *Amount per ton.* Monensin, 25 to 400 grams.

(*a*) *Indications for use.* For improved feed efficiency; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(*b*) *Limitations.* Feed to mature reproducing beef cows. Feed as supplemental feed, either hand-fed in a minimum of 1 pound of feed or mixed in a total ration. For improved feed efficiency, feed continuously at a rate of 50 to 200 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day.

(vii) *Amount per ton.* Monensin, 10 to 40 grams.

(*a*) *Indications for use.* For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(*b*) *Limitations.* For cattle fed in confinement for slaughter, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day.

(ix) *Amount.* To 000986: To make liquid Type B medicated feed containing 400 grams per ton monensin sodium with 150 grams per ton tylosin phosphate used to make a dry Type C medicated feed containing 21.4 to 26.8 grams per ton monensin plus 8 to 10 grams per ton tylosin.

(*a*) *Indications for use.* Improved feed efficiency; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces* (*Corynebacterium*) *pyogenes*.

(*b*) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously at the rate of 8.2 to 10.2 kilograms (18 to 22.5 pounds) of Type C medicated feed per head per day to supply 240 milligrams of monensin and 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate. Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by equines has been fatal. Safe use in unapproved species and breeding cattle has not been established. The liquid medicated feed must bear expiration date of 14 days after date of manufacture. The mixing directions for this liquid medicated feed stored in recirculation or agitation tank systems are as defined in paragraph (d)(12) of this section.

(x) *Amount per ton.* 1,620 grams monensin, USP.

(*a*) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

(*b*) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6–01–082
Sodium chloride (salt)	24.37	6–04–152
Dried cane molasses	20.0	4–04–695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6–02–632
Cane molasses	3.0	4–04–696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix [1]	2.5	
Monensin Type A article, 90.7 grams per pound	0.89	

Ingredient	Percent	International feed No.
Antidusting oil	1.0	

[1] Content of the vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with the published requirements. (For selenium see 21 CFR 573.920; for EDDI see 51 FR 11483 (April 3, 1986).)

(*c*) *Limitations*. Feed at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. The product's effectiveness in cull cows and bulls has not been established.

(xi) *Amount per ton*. Monensin, 10 to 200 grams.

(*a*) *Indications for use*. For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.

(*b*) *Limitations*. For calves excluding veal calves. Feed at a rate of 0.14 to 1.0 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 200 milligrams per head per day.

(xii) *Amount per ton*. Monensin, 10 to 40 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use*. Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

(*b*) *Limitations*. Feed only to cattle being fed in confinement for slaughter. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligrams monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day; and 60 to 90 milligrams of tylosin per head per day.

(xiii) *Amount per ton*. Monensin, 11 to 22 grams.

(A) *Indications for use*. For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations*. Feed continuously to dry and lactating dairy cows in a total mixed ration (''complete feed''). See special labeling considerations in paragraph (d) of this section.

(xiv) *Amount per ton*. Monensin, 11 to 400 grams.

(A) *Indications for use*. For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations*. Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. See special labeling considerations in paragraph (d) of this section.

(4) *Replacement chickens intended for use as cage layers*—(i) *Amount per ton*. Monensin, 90 to 110 grams.

(i)(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(ii) *Amount per ton*. Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 4 to 50 grams.

(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, and improved feed efficiency.

(*b*) *Limitations*. Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton*. Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 50 grams.

(*a*) *Indications for use*. As an aid in the prevention of coccidiosis caused by

E. necatrix, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iv) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium; do not feed to chickens over 16 weeks of age.

(v) *Amount per ton.* Monensin, 90 to 110 grams; plus bacitracin methylene disalicylate, 100 to 200 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). As monensin sodium provided by 000986; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Monensin, 90 to 110 grams; bacitracin methylene disalicylate, 50 grams; plus roxarsone, 22.7 to 45.4 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. Use as sole source of organic arsenic. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. As monensin sodium provided by 000986; bacitracin methylene disalicylate and roxarsone as provided by 046573 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Monensin, 90 to 110 grams; bacitracin methylene disalicylate, 100 to 200 grams; plus roxarsone, 22.7 to 45.4 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Do not feed to laying chickens. Use as sole source of organic arsenic. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. As monensin sodium provided by 000986; bacitracin methylene disalicylate and roxarsone as provided by 046573 in § 510.600(c) of this chapter.

(iv) *Amount per ton.* Monensin, 90 to 110 grams, plus roxarsone, 22.7 to 45.4 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, *and E. maxima*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying chickens. Do not feed to chickens over 16

weeks of age. Poultry should have access to drinking water at all times. Drug overdosage or lack of water may result in leg weakness or paralysis. As monensin sodium provided by 000986; roxarsone as provided by 046573 in § 510.600(c) of this chapter.

(5) *Bobwhite quail*—(i) *Amount per ton.* Monensin, 73 grams.

(ii) *Indications for use.* For the prevention of coccidiosis in growing bobwhite quail caused by *Eimeria dispersa* and *E. Lettyae.*

(iii) *Limitations.* Feed continuously as the sole ration; do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin.

(6) *Goats*—(i) *Amount per ton.* Monensin, 20 grams.

(*a*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria crandallis, E. christenseni,* and *E. ninakohlyakimovae.*

(*b*) *Limitations.* (*1*) *Feed continuously.* Feed only to goats being fed in confinement. Do not feed to lactating goats. Type C feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions, as defined in paragraph (d)(12) of this section. See special labeling considerations in paragraph (d) of this section.

(*2*) An approved physically stable monensin liquid feed will not be subject to the requirements for mixing directions defined in paragraph (d)12) of this section. A manufacturer may secure approval of a physically stable liquid feed by:

(*i*) Either filing an NADA for the product or by establishing a master file containing data to support the stability of its product;

(*ii*) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish physical stability; and

(*iii*) Requesting No. 000986 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the agency will approve the supplemental NADA. The approval will provide a basis for the individual liquid feed manufacturer to manufacture the liquid medicated feed under a medicated feed mill license described in the master file. A manufacturer who seeks to market a physically unstable monensin liquid feed with mixing directions different from the standard established in paragraph (d)(12) of this section may also follow this procedure.

(ii) [Reserved]

(7) Monensin may also be used in combination with:

(i) Decoquinate alone or with tylosin as in § 558.195.

(ii) Melengestrol acetate alone or with tylosin as in § 558.342.

(iii) Ractopamine alone or in combination as in § 558.500.

(iv) Zilpaterol alone or in combination as in § 558.665.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.355, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

§ 558.360 Morantel tartrate.

(a) *Approvals.* Type A medicated articles: 88 grams per pound to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.425 of this chapter.

(c) *Special considerations.* (1) Do not use in Type B or Type C medicated feeds containing bentonite.

(2) Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(d) *Conditions of use*—(1) *Amount.* 0.44 to 4.4 grams of morantel tartrate per pound of feed.

(2) *Indications for use*—(i) *Cattle.* For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

(ii) *Goats.* For removal and control of mature gastrointestinal nematode infections of goats including *Haemonchus*

contortus, *Ostertagia (Teladorsagia) circumcincta*, and *Trichostrongylus axei*.

(3) *Limitations*. Feed as a single therapeutic treatment at 0.44 gram of morantel tartrate per 100 pounds of body weight. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Do not treat cattle within 14 days of slaughter; do not treat goats within 30 days of slaughter.

[46 FR 50950, Oct. 16, 1981, as amended at 47 FR 53352, Nov. 26, 1982; 51 FR 7399, Mar. 3, 1986; 51 FR 9005, Mar. 17, 1986; 52 FR 11642, Apr. 10, 1987; 59 FR 17922, Apr. 15, 1994; 66 FR 47963, Sept. 17, 2001]

§ 558.363 Narasin.

(a) *Approvals*. Type A medicated articles containing specified levels of narasin approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (d) of this section are as follows:

(1) To 000986: 36, 45, 54, 72, and 90 grams per pound, paragraph (d)(1)(i) of this section.

(2) To 000986: 36, 45, 54, 72, and 90 grams per pound, with 10, 20, 50, and 80 percent roxarsone, paragraph (d)(1)(ii) of this section.

(3) To 000986: 36 grams per pound, with 36 grams per pound nicarbazin, paragraph (d)(1)(iii) of this section.

(4) To 016592: 36, 45, 54, 72, and 90 grams per pound, with 2 and 10 grams per pound bambermycins, paragraph (d)(1)(iv) of this section.

(5) To 016592: 45 grams per pound, with 4 and 10 grams per pound bambermycins, and 45.4, 90, and 227 grams per pound roxarsone, paragraph (d)(1)(vii) of this section.

(6) To 046573: 45 grams per pound with 10, 25, 30, 40, 50, 60, or 75 grams per pound bacitracin methylene disalicylate and 45.4, 90, or 227 grams per pound roxarsone, paragraphs (d)(1)(viii) and (d)(1)(ix) of this section.

(7) To 046573: 36, 45, 54, 72, or 90 grams per pound, with 10, 25, 40, or 50 grams per pound bacitracin zinc, paragraph (d)(1)(x) of this section.

(b) *Tolerances*. See § 556.428 of this chapter.

(c) [Reserved]

(d) *Conditions of use*. It is used as follows:

(1) *Broiler chickens*—(i) *Amount per ton*. Narasin, 54 to 72 grams.

(A) *Indications for use*. For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(B) *Limitations*. For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal.

(ii) *Amount per ton*. Narasin, 54 to 72 grams, plus roxarsone 45.4 grams (0.005 percent).

(A) *Indications for use*. For the prevention of coccidiosis in broiler chickens caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* including some field strains of *E. tenella* which are more susceptible to roxarsone combined with narasin than to narasin alone.

(B) *Limitations*. For broiler chickens only; feed continuously as the sole ration; do not feed to laying chickens; may be fatal if accidentally fed to adult turkeys or to horses; withdraw 5 days before slaughter; as sole source of organic arsenic; not approved for use with pellet binders.

(iii) *Amount per ton*. Narasin, 27 to 45 grams, plus nicarbazin, 27 to 45 grams.

(A) *Indications for use*. For the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(B) *Limitations*. For broiler chickens only. Feed continuously as the sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Withdraw 5 days before slaughter. The 2 drugs can be combined only at a 1:1 ratio for the 27 to 45 grams per ton range. Only granular nicarbazin as provided by No. 000986 in § 510.600(c) of this chapter may be used in the combination.

(iv) *Amount per ton*. Narasin, 54 to 72 grams, plus bambermycins, 1 to 2 grams.

(A) *Indications for use*. For prevention of coccidiosis caused by *Eimeria*

necatrix, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as the sole ration. May be fatal if fed to adult turkeys, horses, or other equines. Narasin as provided by No. 000986; bambermycins by No. 016592 in § 510.600(c) of this chapter.

(v) *Amount per ton.* Narasin 54 to 72 grams, roxarsone 22.7 to 45.4 grams, and bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, for increased rate of weight gain, and for improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Use as sole source of organic arsenic. Drug overdose or lack of water may result in leg weakness. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by 000986, roxarsone by 046573, bacitracin methylene disalicylate by 046573 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Narasin 54 to 72 grams, and bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati*, *E. necatrix*, and *E. tenella*, for increased rate of weight gain, and for improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by 000986, bacitracin methylene disalicylate by 046573 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Narasin 54 to 72 grams, bambermycins 1 to 2 grams, and roxarsone 22.7 to 45.4 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. mivati*, *E. acervulina*, *E. maxima*, and *E. brunetti*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys or horses or other equines access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Narasin as provided by 000986 in § 510.600(c) of this chapter, bambermycins by 016592, and roxarsone by 046573.

(viii) *Amount per ton.* Narasin, 54 to 72 grams, and bacitracin methylene disalicylate, 50 grams, with roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water intake may result in leg weakness or paralysis. Narasin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573 in § 510.600(c) of this chapter.

(ix) *Amount per ton.* Narasin, 54 to 72 grams, and bacitracin methylene disalicylate, 100 to 200 grams, with roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an

aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water intake may result in leg weakness or paralysis. Narasin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573 in § 510.600(c) of this chapter.

(x) *Amount per ton.* Narasin, 54 to 72 grams and bacitracin zinc, 4 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin as provided by 000986, bacitracin zinc by 046573 in § 510.600(c) of this chapter.

(xi) *Amount per ton.* Narasin, 54 to 72 grams, plus tylosin, 4 to 50 grams.

(A) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, for increased rate of weight gain, and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin sodium and tylosin phosphate as provided by 000986 in § 510.600(c) of this chapter.

(2) Narasin may also be used for broilers in combination with:

(i) Nicarbazin with lincomycin as in § 558.366.

(ii) Nicarbazin and bacitracin methylene disalicylate as in § 558.366.

(iii) Bacitracin methylene disalicylate, nicarbazin, and roxarsone as in § 558.366.

(iv) Nicarbazin and roxarsone as in § 558.366.

[51 FR 29098, Aug. 14, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.363, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.364 Neomycin sulfate.

(a) *Approvals.* Type A medicated article: 325 grams per pound to 000009 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.430 of this chapter.

(c) [Reserved]

(d) *Conditions of use.* Neomycin sulfate is used as follows:

Neomycin Sulfate	Combination	Indications for Use	Limitations	Sponsor
(1) 250 to 2,250 grams per ton (g/t) of dry type C feed..	.....	Cattle, swine, sheep, and goats. For treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin..	To provide 10 milligrams (mg) of neomycin sulfate per pound of body weight per day for a maximum of 14 days. The concentration of neomycin sulfate required in medicated feed must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects feed consumption. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in dry feeds only. Not for use in liquid feed supplements..	000009
(2) 400 to 2,000 g/t of type C milk replacer..	.....	Do.	To provide 10 mg of neomycin sulfate per pound of body weight per day for a maximum of 14 days. Amount consumed will vary depending on animal's consumption and weight. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Discontinue treatment prior to slaughter as follows: Cattle 1 day, swine 3 days, sheep 2 days, and goats 3 days. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle or lactating dairy goats. Do not use in female dairy cattle 20 months of age or older or female dairy goats 12 months of age or older. For use in milk replacers only..	000009

[64 FR 70576, Dec. 17, 1999, as amended at 65 FR 45881, July 26, 2000]

§ 558.365 Nequinate.

(a) *Approvals.* Type A medicated articles: 4 percent to No. 051311 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.440 of this chapter.

(c) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Conditions of use.* It is used as follows:

(1) *Broiler or fryer chickens*—(i) *Amount per ton.* Nequinate, 18.16 grams.

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(iii) *Limitations.* Feed continuously as the sole ration.

(2) *Roaster chickens or replacement chickens for caged layers*—(i) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(iii) *Limitations.* Feed continuously as the sole ration; do not feed to chickens over 16 weeks of age.

[40 FR 13959, Mar. 27, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2685, Jan. 26, 1987; 66 FR 45167, Aug. 28, 2001; 70 FR 32489, June 3, 2005]

§ 558.366 Nicarbazin.

(a) *Specifications.* Type A medicated articles containing 25 percent nicarbazin.

(b) *Approvals.* See Nos. 000986, 060728, and 066104 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Related tolerances.* See § 556.445 of this chapter.

(d) *Conditons of use.* It is used in chicken feed as follows:

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45	Narasin 27 to 45	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, E. mivati.*.	Sec. 558.363(d)(1)(iii)	000986
	Narasin 27 to 45 and bacitracin methylene disalicylate 4 to 50.	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, E. mivati*; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Narasin and nicarbazin as provided by 000986, bacitracin methylene disalicylate by 046573.	000986
	Narasin 27 to 45 and bacitracin methylene disalicylate 50..	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and nicarbazin as provided by No. 000986, bacitracin methylene disalicylate by No. 046573 in § 510.600(c) of this chapter..	046573

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Narasin 27 to 45 and bacitracin methylene disalicylate 100 to 200..	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and nicarbazin as provided by No. 000986, bacitracin methylene disalicylate by No. 046573 in § 510.600(c) of this chapter..	046573
	Narasin 27 to 45, bacitracin methylene disalicylate 50, and roxarsone 22.7 to 45.4. .	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Use as sole source of organic arsenic. Narasin and nicarbazin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573..	046573
	Narasin 27 to 45, and bambermycins 1 to 2.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima, E. necatrix*, and *E. brunetti*) coccidiosis; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter. Bambermycins provided by No. 016592; nicarbazin and narasin by No. 066104 in § 510.600(c) of this chapter.	000986
	Narasin 27 to 45 and Lincomycin 2 to 4.	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, E. mivati*; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Narasin and nicarbazin as provided by 000986, lincomycin by 000009.	000986

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Narasin 27 to 45 and roxarsone 22.7 to 45.4.	Broiler chickens; for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Use as sole source of organic arsenic. Narasin and nicarbazin as provided by 000986, roxarsone by 046573..	000986
90.8 to 181.6 (0.01 to 0.02 pct).	Bacitracin methylene disalicylate 4 to 50 and roxarsone 22.7 to 45.4.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix*, and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency, and improved pigmentation.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Feed as the sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; do not use in flushing mashes. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Nicarbazin as provided by No. 066104; bacitracin methylene disalicylate and roxarsone by No. 046573 in § 510.600(c) of this chapter.	066104
	Penicillin 2.4 to 50 ...	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix*, and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. Do not feed to chickens producing eggs for human consumption. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Penicillin as procaine penicillin G. Nicarbazin and penicillin as provided by No. 066104 in § 510.600(c) of this chapter.	066104

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Penicillin 2.4 to 50 and roxarsone 22.7 to 45.4.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix*, and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency, and improved pigmentation.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Feed as the sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; do not use in flushing mashes. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Penicillin as procaine penicillin G. Nicarbazin and penicillin as provided by No. 066104; roxarsone by No. 046573 in § 510.600(c) of this chapter.	066104
113.5 (0.0125 pct).	.....	Chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter.	000986 060728 066104
	Bacitracin methylene disalicylate 4 to 50..	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix*, and *E. brunetti*) coccidiosis; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter..	046573
	Bacitracin methylene disalicylate 30.	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; for increased rate of weight gain and improved feed efficiency.	.....do	060728 066104
	Bacitracin methylene disalicylate 50..	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix*, and *E. brunetti*) coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter..	046573

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin zinc 4 to 50..	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency..	For broiler chickens only. Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Discontinue medication 4 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Nicarbazin as provided by 066104, bacitracin zinc by 046573..	066104 046573
	Bambermycins 1 to 2	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter. Nicarbazin as provided by 066104..	057926
	Bambermycins 1 to 2	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.	016592
	Lincomycin 2 (0.00044 pct).	Broiler chickens; aid in preventing outbreaks of secal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; for increased rate of weight gain..	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter..	060728 066104
	Roxarsone 22.7 (0.0025)..	.....do	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; as sole source of organic arsenic; do not use a treatment for coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 5 days before slaughter.	060728 066104
	Roxarsone 22.7 (0.0025) plus lincomycin 2 (0.0004)..	.....do	.....do	060728 066104

[42 FR 56729, Oct. 28, 1977; 43 FR 1942, Jan. 13, 1978, as amended at 44 FR 40887, July 13, 1979; 50 FR 13562, Apr. 5, 1985; 51 FR 7399, Mar. 3, 1986; 54 FR 1928, Jan. 18, 1989; 60 FR 29483, June 5, 1995; 61 FR 1832, Jan. 24, 1996; 61 FR 14021, Mar. 29, 1996; 61 FR 14483, Apr. 2, 1996; 62 FR 29011, May 29, 1997; 63 FR 13124, Mar. 18, 1998; 63 FR 57248, Oct. 27, 1998; 64 FR 4966, Feb. 2, 1999; 64 FR 18574, Apr. 15, 1999; 64 FR 20164, Apr. 26, 1999; 64 FR 49384, Sept. 13, 1999; 65 FR 11889, Mar. 7, 2000; 66 FR 46706, Sept. 7, 2001; 66 FR 47962, Sept. 17, 2001; 66 FR 63500, Dec. 7, 2001; 67 FR 30327, May 6, 2002; 71 FR 16224, Mar. 31, 2006; 71 FR 27957, May 15, 2006; 73 FR 15884, Mar. 26, 2008; 75 FR 7555, Feb. 22, 2010]

§ 558.369 Nitarsone.

(a) *Approvals.* Type A medicated articles: 50 percent to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.60 of this chapter.

(c) [Reserved]

(d) *Conditions of use.* It is used as follows:

(1) *Chickens and turkeys*—(i) *Amount.* Nitarsone, 0.01875 percent.

(ii) *Indications for use.* As an aid in the prevention of blackhead.

(iii) *Limitations.* Early medication is essential to prevent spread of disease. Adequate drinking water must be provided near feeder at all times. The drug is not effective in preventing blackhead in birds infected more than 4 or 5 days. Discontinue use 5 days before slaughtering animals for human consumption to allow elimination of the drug from edible tissues. The drug is dangerous for ducks, geese, and dogs. Overdosage or lack of water may result in leg weakness or paralysis. Use as sole source of arsenic.

(2) *Turkeys*—(i) *Amount.* Nitarsone 0.01875 percent, plus bacitracin methylene disalicylate or bacitracin zinc 4 to 50 grams per ton.

(ii) *Indications for use.* As an aid in the prevention of blackhead, and for increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* For growing turkeys. Feed continuously as sole ration. Early medication is essential to prevent spread of disease. Adequate drinking water must be provided near feeders at all times. Overdosage or lack of water may result in leg weakness or paralysis. The drug is not effective in preventing blackhead in birds infected more than 4 or 5 days. Discontinue use 5 days before slaughtering animals for human consumption to allow elimination of the drug from edible tissues. The drug is dangerous for ducks, geese, and dogs. Use as sole source of arsenic.

[46 FR 47535, Sept. 29, 1981, as amended at 47 FR 14152, Apr. 2, 1982; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 8460, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992; 63 FR 39028, July 21, 1998; 71 FR 16223, Mar. 31, 2006]

§ 558.415 Novobiocin.

(a) *Approvals.* Type A medicated articles: 25 grams of activity per pound to 000009 in § 510.600(c) of this chapter. Type B medicated feeds: 17.5 grams per pound to 000009 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.460 of this chapter.

(c) *Conditions of use.* It is used in animal feeds as follows:

(1) *Chickens*—(i) *Amount.* Novobiocin, 6–7 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 10–14 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(2) *Turkeys*—(i) *Amount.* Novobiocin, 4–5 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying turkeys; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 5–8 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the control of recurring outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin following initial treatment with 7–8 mgs. per pound body weight per day.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(iii) *Amount.* Novobiocin, 7–8 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infection susceptible to novobiocin; treatment of acute outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(3) *Mink*—(i) *Amount.* 20 mgs. per lb. body weight per day.

(ii) *Indications for use.* For treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.

(iii) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed for 7 days.

(4) *Ducks*—(i) *Amount.* Novobiocin, 350 grams per ton.

(ii) *Indications for use.* Control of infectious serositis and fowl cholera in ducks caused by *Pasteurella anatipestifer* and *P. multocida,* susceptible to novobiocin.

(iii) *Limitations.* Administer, as sole ration, for 5 to 7 days, continue medication for 14 days if necessary, repeat if reinfection occurs; discontinue use at least 3 days before slaughter; not for use in laying ducks.

[40 FR 13959, Mar. 27, 1975, as amended at 45 FR 42263, June 24, 1980; 51 FR 7399, Mar. 3, 1986; 52 FR 36402, Sept. 29, 1987]

§ 558.430 Nystatin.

(a) *Approvals.* Type A medicated articles: 20 grams of activity per pound to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.470 of this chapter.

(c) *Conditions of use.* It is used for chickens and turkeys as follows:

(1) *Amount.* 50 grams per ton.

(i) *Indications for use.* Chickens and turkeys; aid in control of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys.

(2) *Amount.* 100 grams per ton.

(i) *Indications for use.* Chickens and turkeys; treatment of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys; to be fed for 7 to 10 days.

[41 FR 11002, Mar. 15, 1976, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 53 FR 40729, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992]

§ 558.435 Oleandomycin.

(a) *Approvals.* Type A medicated articles: 5 grams of activity per pound to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.480 of this chapter.

(c) *Special considerations.* Do not use bentonite in Type B or Type C medicated feeds containing oleandomycin. Oleandomycin refers to oleandomycin or feed-grade oleandomycin.

(d) *Conditions of use.* It is used in animal feed as follows:

(1) *Chickens and turkeys*—(i) *Amount per ton.* Oleandomycin, 1 to 2 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency for broiler chickens and growing turkeys.

(2) *Swine*—(i) *Amount per ton.* Oleandomycin, 5 to 11.25 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency in growing-finishing swine.

[40 FR 13959, Mar. 27, 1975, as amended at 44 FR 40283, July 10, 1979; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 66 FR 47963, Sept. 17, 2001]

§ 558.450 Oxytetracycline.

(a) *Approvals.* Type A medicated articles:

(1) 10, 20, 30, 50, 100, and 200 grams per pound to No. 066104 in § 510.600(c) of this chapter.

(2) 50, 100, and 200 grams per pound to No. 048164 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) In accordance with § 558.5 labeling shall bear the statement: ''FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS.''

(2) The articles in paragraph (a)(1) of this section contain an amount of mono-alkyl (C_8–C_{18}) trimethylammonium oxytetracycline expressed in terms of an equivalent

amount of oxytetracycline hydrochloride or an amount of oxytetracycline dihydrate base expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(3) 50-, 100-, and 200-gram per pound articles in paragraph (a)(2) of this section contain oxytetracycline dihydrate expressed in terms of an equivalent amount of oxytetracycline hydrochloride. Another 100-gram per pound article in paragraph (a)(2) of this section contains oxytetracycline hydrochloride.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 grams per ton (g/ton).	Chickens: For increased rate of weight gain and improved feed efficiency..	Feed continuously; do not feed to chickens producing eggs for human consumption..	066104, 048164
(ii) 100 to 200 g/ton	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae* and control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline..	Feed continuously for 7 to 14 days (d); do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter..	066104, 048164
(iii) 400 g/ton	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter..	066104, 048164
(iv) 500 g/ton	Chickens: For reduction of mortality due to air sacculitis (air sac infection) caused by *E. coli* susceptible to oxytetracycline..	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds, withdraw 3 d before slaughter..	066104, 048164

(2) *Turkeys*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton ...	Growing turkeys: For increased rate of weight gain and improved feed efficiency..	Feed continuously; do not feed to turkeys producing eggs for human consumption..	066104, 048164
(ii) 100 g/ton	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	066104, 048164
(iii) 200 g/ton	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; for No. 066104 withdraw 5 d before slaughter; for No. 048164 zero-day withdrawal time; do not feed to turkeys producing eggs for human consumption..	066104, 048164
(iv) 25 milligrams/pound (mg/lb) of body weight daily.	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; for No. 066104 withdraw 5 d before slaughter; for No. 048164 zero-day withdrawal time; do not feed to turkeys producing eggs for human consumption..	066104, 048164

(3) *Swine*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/ton ...	Swine: For increased rate of weight gain and improved feed efficiency..	Feed continuously.	066104, 048164
(ii) 10 mg/lb of body weight daily.	1. Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d.	066104, 048164
.....	2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline..	Feed continuously for 14 d.	066104, 048164

(4) *Cattle*—

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 0.05 to 0.1 mg/lb of body weight daily.	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency..	Feed continuously in milk replacer or starter feed..	066104, 048164
(ii) 10 mg/lb of body weight daily.	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; for No. 048164, withdraw 5 d before slaughter; for No. 066104, zero-day withdrawal time..	066104, 048164
.....	2. Calves: For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d in milk replacer or starter feed; for No. 048164, withdraw 5 d before slaughter; for No. 066104, zero-day withdrawal time..	066104, 048164
(iii) 25 mg/head/day.	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency..	Feed continuously.	066104, 048164
(iv) 75 mg/head/day.	Growing cattle (over 400 lb): For increased rate of weight gain, improved feed efficiency, and reduction of liver condemnation due to liver abscesses..	Feed continuously.	066104, 048164

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(v) 0.5 to 2.0 g/head/day.	Cattle: For prevention and treatment of the early stages of shipping fever complex..	Feed 3 to 5 d before and after arrival in feedlots..	066104, 048164

(5) *Minor species—*

Oxytetracycline amount	Indications for use	Limitations	Sponsor
(i) 10 to 20 g/ton ...	Sheep: For increased rate of weight gain and improved feed efficiency..	Feed continuously.	066104, 048164
(ii) 10 mg/lb of body weight daily.	Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter..	066104, 048164
(iii) 200 mg/colony	Honey bees: For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline..	Remove at least 6 weeks prior to main honey flow..	066104, 048164
(iv) 250 mg/kilogram of fish/day (11.35 g/100 lb of fish/day).	Pacific salmon: For marking of skeletal tissue..	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days; fish not to be liberated for at least 7 d following the last administration of medicated feed..	066104
(v) 2.5 to 3.75 g/100 lb of fish/day.	1. Salmonids: For control of ulcer disease caused by *Hemophilus piscium*, furunculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *A. liquefaciens*, and pseudomonas disease..	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed..	066104
.....	2. Catfish: For control of bacterial hemorrhagic septicemia caused by *A. liquefaciens* and pseudomonas disease..	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 16.7 °C (62 °F)..	066104
(vi) 3.75 g/100 lb of fish/day.	1. Freshwater-reared salmonids: For control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum*..	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed..	066104

Oxytetracycline amount	Indications for use	Limitations	Sponsor
.....	2. Freshwater-reared *Oncorhynchus mykiss*: For control of mortality due to columnaris disease associated with *Flavobacterium columnare*..	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed..	066104
(vii) 1 g/lb of medicated feed.	Lobsters: For control of gaffkemia caused by *Aerococcus viridans*..	Administer as sole ration for 5 consecutive days; withdraw medicated feed 30 d before harvesting lobsters..	066104

(6) Oxytetracycline may be used in accordance with the provisions of this section in the combinations as follows:

(i) Carbadox as in § 558.115.

(ii) Lasalocid as in § 558.311.

(iii) Melengestrol acetate as in § 558.342.

(iv) Robenidine hydrochloride as in § 558.515.

(v) Salinomycin as in § 558.550.

[61 FR 51590, Oct. 3, 1996, as amended at 63 FR 41192, Aug. 3, 1998; 66 FR 32740, June 18, 2001; 66 FR 45167, Aug. 28, 2001; 66 FR 47963, Sept. 17, 2001; 67 FR 51081, Aug. 7, 2002; 69 FR 28821, May 19, 2004; 69 FR 51173, Aug. 18, 2004; 69 FR 62407, Oct. 26, 2004; 71 FR 27958, May 15, 2006; 71 FR 44887, Aug. 8, 2006; 71 FR 53006, Sept. 8, 2006; 72 FR 70774, Dec. 13, 2007; 73 FR 45875, Aug. 7, 2008]

§ 558.455 Oxytetracycline and neomycin.

(a) *Specifications.* Type A medicated articles containing oxytetracycline equivalent to 50 grams per pound (g/lb) oxytetracycline hydrochloride and 50 g/lb neomycin sulfate or oxytetracycline equivalent to 100 g/lb oxytetracycline hydrochloride and 100 g/lb neomycin sulfate.

(b) *Sponsors.* See Nos. 048164 and 066104 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.430 and 556.500 of this chapter.

(d) *Special considerations.* Cattle feeds shall bear the following warning statement: ''Use of more than one product containing neomycin or failure to follow withdrawal times may result in illegal drug residues.''

(e) *Indications for use*—(1) *Chickens.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount in grams per ton of feed	Indications for use	Limitations	Sponsors
(i) 10 to 50	Chickens: For increased rate of weight gain and improved feed efficiency..	Feed continuously; do not feed to chickens producing eggs for human consumption; in low calcium feeds withdraw 3 days before slaughter..	048164 066104
(ii) 100 to 200	Chickens: For control of infectious synovitis caused by *Mycoplasma synoviae*; control of fowl cholera caused by *Pasteurella multocida* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feed, withdraw 3 d before slaughter..	048164 066104
(iii) 400	Chickens: For control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption; in low calcium feeds, withdraw 3 d before slaughter..	048164 066104
(iv) 500	Chickens: For reduction of mortality due to air sacculitis (air-sac- infection) caused by *E. coli* susceptible to oxytetracycline..	Feed continuously for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter..	048164 066104

(2) *Turkeys.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 50 grams per ton (g/ton) of feed.	Growing turkeys: For increased rate of weight gain and improved feed efficiency..	Feed continuously; do not feed to turkeys producing eggs for human consumption..	048164 066104
(ii) 100 g/ton of feed	Turkeys: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption..	048164 066104
(iii) 200 g/ton of feed	Turkeys: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption..	048164 066104
(iv) To provide 25 milligrams per pound (mg/lb) of body weight daily..	Turkeys: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline..	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter; do not feed to turkeys producing eggs for human consumption..	048164 066104

(3) *Swine*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 50 g/ton of feed.	Swine: For increased rate of weight gain and improved feed efficiency..	Feed continuously.	048164 066104
(ii) To provide 10 mg/lb of body weight daily..	1. Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin..	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter..	048164 066104
.....	2. Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline..	Feed continuously for not more than 14 d; withdraw 5 d before slaughter..	048164 066104

(4) *Cattle and sheep*. It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) 10 to 20 g/ton of feed.	Sheep: For increased rate of weight gain and improved feed efficiency..	Feed continuously.	048164 066104
(ii) To provide 0.05 to 0.1 mg/lb of body weight daily..	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency..	Feed continuously; in milk replacers or starter feed..	048164 066104
(iii) To provide 10 mg/lb of body weight daily..	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin..	Feed continuously for 7 to 14 d; in feed or milk replacers. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter..	048164 066104

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
.....	2. Calves (up to 250 lb): For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin..	Feed continuously for 7 to 14 d; in milk replacers or starter feed. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter..	048164 066104
.....	3. Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin..	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter..	048164 066104
(iv) To provide 25 mg/head/day.	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency..	Feed continuously.	048164 066104
(v) To provide 75 mg/head/day.	Growing cattle (over 400 lb): For increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses..	Feed continuously.	048164 066104
(vi) To provide 0.5 to 2.0 g/head/ day.	Cattle: For prevention and treatment of the early stages of shipping fever complex..	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older..	048164 066104

[71 FR 16225, Mar. 31, 2006, as amended at 74 FR 40724, Aug. 13, 2009]

§ 558.460 Penicillin.

(a) *Specifications.* As penicillin procaine G or feed grade penicillin procaine.

(b) *Sponsors.* Type A medicated articles: To 066104, 100 and 227 grams per pound. To 046573, 100 and 227 grams per pound.

(c) Related tolerances. See § 556.510 of this chapter.

(d) *Conditions of use.* (1) It is used as follows:

Penicillin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 2.4 to 50	.....	Chickens, turkeys, and pheasants; for increased rate of weight gain and improved feed efficiency..	Do not feed to poultry producing eggs for human consumption..	000069, 046573.
(ii) 5 to 20	.....	Quail; for increased rate of weight gain and improved feed efficiency..	Quail; not over 5 weeks of age.	Do.
(iii) 10 to 50	.....	Swine; for increased rate of weight gain and improved feed efficiency..	.....	Do.

(2) Penicillin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium plus ethopatbate in accordance with § 558.58.

(iii) Hygromycin B in accordance with § 558.274.

(iv) Nicarbazin alone or with roxarsone as in § 558.366.

(v) Roxarsone and zoalene in accordance with § 558.680.

(vi) Zoalene in accordance with § 558.680.

[41 FR 11004, Mar. 15, 1976, as amended at 42 FR 18618, Apr. 8, 1977; 42 FR 36995, July 19, 1977; 47 FR 42103, Sept. 24, 1982; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 58 FR 30120, May 26, 1993; 60 FR 39847, Aug. 4, 1995; 63 FR 36179, July 2, 1998; 65 FR 45880, July 26, 2000; 66 FR 47963, Sept. 17, 2001; 71 FR 16227, Mar. 31, 2006]

§ 558.464 Poloxalene.

(a) *Approvals.* (1) Dry Type A medicated articles: 53 percent to 000069 in § 510.600(c) of this chapter.

(2) Liquid Type A medicated articles: 99.5 percent to 000069 in § 510.600(c) of this chapter.

(b) *Conditions of use.* (1) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle.

(2) Poloxalene dry Type A article and liquid Type A article must be thoroughly blended and evenly distributed in feed prior to use. This may be accomplished by adding the Type A article to a small quantity of feed, mixing thoroughly, then adding this mixture to the remaining feed and again mixing thoroughly. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily and continued during exposure to bloat producing conditions. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat dosage if animals are exposed to bloat-producing conditions more than 12 hours after the last treatment. Do not exceed the higher dosage levels in any 24-hour period.

[40 FR 39857, Aug. 29, 1975, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 56 FR 50654, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995]

§ 558.465 Poloxalene free-choice liquid Type C feed.

(a) *Approvals.* Type A medicated articles: 99.5 percent to 066104 in § 510.600(c) of this chapter.

(b) *Conditions of use.* (1) For control of legume (alfalfa, clover) and wheat pasture bloat in cattle, use 7.5 grams of poloxalene per pound of liquid Type C feed (1.65 percent weight/weight). Each animal must consume 0.2 pound of Type C feed per 100 pounds of body weight daily for adequate protection.

(2) For control of legume (alfalfa, clover) bloat in cattle grazing of prebloom legumes, use 10.00 grams of poloxalene per pound of liquid Type C feed (2.2 percent weight/weight). Each animal must consume 0.15 pound of Type C feed per 100 pounds of body weight daily for adequate protection. If consumption exceeds 0.2 pound of Type C feed per 100 pounds of body weight daily, cattle should be changed to a Type C feed containing 7.5 grams of poloxalene per pound.

(3) Poloxalene liquid Type A article must be thoroughly blended and evenly distributed into a liquid Type C feed and offered to cattle in a covered liquid Type C feed feeder with lick wheels. The formula for the liquid Type C feed, on a weight/weight basis, is as follows: Ammonium polyphosphate 2.66 percent, phosphoric acid (75 percent) 3.37 percent, sulfuric acid 1.00 percent, water 10.00 percent, and molasses sufficient to make 100.00 percent, vitamins A and D and/or trace minerals may be added. One free-turning lick wheel per 25 head of cattle must be provided.

(4) The medicated liquid Type C feed must be introduced at least 2 to 5 days before legume consumption to accustom the cattle to the medicated liquid Type C feed and to lick wheel feedings. If the medicated liquid wheel Type C feed feeding is interrupted, this 2- to 5-day introductory feeding should be repeated.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 21281, Apr. 26, 1977; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 56 FR 50654, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 66 FR 47963, Sept. 17, 2001]

§ 558.485 Pyrantel.

(a) *Specifications.* Type A medicated articles containing 9.6, 19.2, 48, or 80 grams per pound pyrantel tartrate.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section:

(1) No. 066104: 9.6, 19.2, 48, and 80 grams per pound for use as in paragraph (e)(1) of this section.

(2) [Reserved]

(3) Nos. 016968, and 017790: 9.6 and 19.2 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(4) [Reserved]

(5) No. 051311: 19.2 and 48 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(6) Nos. 034936 and 046987: 9.6 and 19.2 grams per pound for use as in paragraphs (e)(1)(i) and (e)(1)(ii) of this section.

(7) Nos. 000069 and 017135: 48 grams per pound for use as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See §556.560 of this chapter.

(d) *Special considerations.* (1) See §500.25 of this chapter. Consult a veterinarian before using in severely debilitated animals.

(2) Do not mix in Type B or Type C medicated feeds containing bentonite.

(e) *Conditions of use.* It is used as follows:

(1) *Swine*—(i) *Amount per ton.* 96 grams (0.0106 percent).

(A) *Indications for use.* Aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* Feed continuously as the sole ration in a Type C feed; withdraw 24 hours prior to slaughter.

(ii) *Amount per ton.* 96 grams (0.0106 percent).

(A) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) infections.

(B) *Limitations.* Feed for 3 days as the sole ration in a Type C feed; withdraw 24 hours prior to slaughter.

(iii) *Amount per ton.* 800 grams (0.0881 percent).

(A) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* As sole ration for a single therapeutic treatment in Type C feed; feed at the rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb, and 5 lb of feed per head for animals 200 lb or over; withdraw 24 hours prior to slaughter.

(iv) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and carbadox, 50 grams (0.0055 percent).

(A) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* Do not feed to swine weighing over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in Type C feeds containing less than 15 percent crude protein.

(v) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and tylosin, 40 to 100 grams, as tylosin phosphate.

(A) *Indications for use.* For prevention of swine dysentery (vibrionic); aid in the prevention of migration and establishment of large roundworms (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum spp.*) infections.

(B) *Limitations.* Use 100 grams tylosin per ton for at least 3 weeks followed by 40 grams tylosin per ton until market weight; withdraw 24 hours before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(vi) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and tylosin 40 to 100 grams, as tylosin phosphate.

(A) *Indications for use.* Treatment and control of swine dysentery (vibrionic); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum spp.*) infections.

(B) *Limitations.* Administer tylosin in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 grams per gallon in drinking water for 3 to 10 days, 40 to 100 grams tylosin per ton in feed for 2

to 6 weeks; withdraw 24 hours before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(vii) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 40 grams, as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For control of swine dysentery; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(viii) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 grams, then 40 grams, as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For treatment and control of swine dysentery; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed 100 grams per ton for 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(ix) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 grams, as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For treatment of swine dysentery; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed 100 grams per ton 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(x) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 or 40 grams.

(A) *Indications for use.* For treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) infections.

(B) *Limitations.* Administer in accordance with paragraph (c)(2)(i), (c)(2)(ii), or (c)(2)(iii) of § 558.325 and paragraph (e)(1)(ii)(B) of this section.

(xi) *Amount per ton.* Pyrantel tartrate, 800 grams (0.0881 percent) and lincomycin, 100 or 40 grams.

(A) *Indications for use.* For treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Administer in accordance with paragraph (c)(2)(i), (c)(2)(ii), or (c)(2)(iii) of § 558.325 and paragraph (e)(1)(iii)(B) of this section.

(xii) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 200 grams as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For the reduction in severity of swine mycoplasma pneumonia caused by *Mycoplasma hyopneumoniae;* aid in the prevention of migration and establishment of large roundworms (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed as sole ration for 21 days; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter; consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(C) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(2) *Horses*—(i) *Amount.* Feed continuously at the rate of 1.2 milligrams per pound (2.64 milligrams per kilogram) of body weight.

(A) *Indications for use.* Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris*, and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).

(B) *Limitations.* Administer either as a top-dress (not to exceed 20,000 grams per ton) or mixed in the horse's daily grain ration (not to exceed 1,200 grams per ton) during the time that the animal is at risk of exposure to internal parasites. Not for use in horses intended for food. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(ii) [Reserved]

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.485, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.500 Ractopamine.

(a) *Specifications.* Type A medicated articles containing 9 or 45 grams of ractopamine hydrochloride per pound.

(b) *Approvals.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.570 of this chapter.

(d) *Special considerations.* (1) Labeling of Type B and Type C feeds shall bear the following: ''Not for animals intended for breeding.''

(2) Labeling of Type B and Type C swine feeds shall bear the following:

(i) ''No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.5 g/ton.''

(ii) ''Ractopamine may increase the number of injured and/or fatigued pigs during marketing.''

(3) Labeling of Type B and Type C tom turkey feeds shall bear the following: ''No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.6 g/ton.''

(4) Tylosin in combinations as tylosin phosphate.

(5) Ractopamine liquid Type B cattle feeds may be manufactured from dry ractopamine Type A articles. The liquid Type B feeds must be maintained at a pH of 4.5 to 7.5 or, if in combination with monensin and/or tylosin, at a pH of 4.5 to 6.0. Mixing directions for liquid Type B feeds requiring recirculation or agitation: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(e) *Conditions of use*—(1) *Swine*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.5 to 9		For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.	Feed continuously as sole ration.	000986
(ii) 4.5 to 9	Tylosin 40 or 100	Finishing swine: As in paragraph (e)(1)(i) of this section; and for control of swine dysentery associated with *Brachyspira hyodysenteriae* and porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis*..	Feed 100 grams per tons (g/ton) continuously as sole ration for at least 3 weeks followed by 40 g/ton until market weight..	000986

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iii) 4.5 to 9	Tylosin 100	Finishing swine: As in paragraph (e)(1)(i) of this section; and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *L. intracellularis*..	Feed continuously as sole ration for 21 days..	000986
(iv) 4.5 to 9	Tylosin ..... 40 to 100	Finishing swine: As in paragraph (e)(1)(i) of this section; for treatment and control of swine dysentery associated with *B. hyodysenteriae* and for control of porcine proliferative enteropathies (PPE, ileitis) associated with *L. intracellularis*..	Feed continuously as sole ration for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water as in § 520.2640(d)(3) of this chapter..	000986

(2) *Cattle*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed..	000986
(ii) 8.2 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii*..	As in paragraph (e)(2)(i) of this section; see paragraph §§ 558.355(d) of this chapter..	000986
(iii) [Reserved].				
(iv) 8.2 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*..	As in paragraph (e)(2)(i) of this section; see §§ 558.355(d) and 558.625(c) of this chapter..	000986
(v) [Reserved].				
(vi) 9.8 to 24.6	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	000986
(vii) 9.8 to 24.6 ...	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii*..	As in paragraph (e)(2)(vi) of this section; see paragraph §§ 558.355(d) of this chapter..	000986

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(viii) 9.8 to 24.6 ..	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat)..	As in paragraph (e)(2)(vi) of this section; see §§ 558.342(d) and 558.355(d) of this chapter. Melengestrol acetate as provided by No. 000009 or 021641 in § 510.600(c) of this chapter..	000986 021641
(ix) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*..	As in paragraph (e)(2)(vi) of this section; see §§ 558.355(d) and 558.625(c) of this chapter..	000986
(x) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*; and for suppression of estrus (heat)..	As in paragraph (e)(2)(vi) of this section; see paragraphs §§ 558.342(d), 558.355(d) and 558.625(c) of this chapter. Melengestrol acetate as provided by Nos. 000009 and 021641 in § 510.600(c) of this chapter..	000986, 021641
(xi) Not to exceed 800; to provide 70 to 400 mg/head/day..	.....	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section..	Top dress in a minimum of 1.0 lb of medicated feed..	000986
(xii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day..	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*..	Top dress ractopamine in a minimum of 1.0 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See § 558.355(d)..	000986
(xiii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10..	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*..	Top dress ractopamine in a minimum of 1.0 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See §§ 558.355(d) and 558.625(c)..	000986

(3) *Turkeys*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 11.8 (5 to 13 ppm).	.....	Finishing hen turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 7 to 14 days prior to slaughter..	Feed continuously as sole ration during the last 7 to 14 days prior to slaughter..	000986
(ii) 4.6 to 11.8 (5 to 13 ppm).	.....	Finishing tom turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 14 days prior to slaughter..	Feed continuously as sole ration during the last 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality..	000986
(iii) 4.6 to 11.8 (5 to 13 ppm).	Monensin 54 to 90 ...	Finishing hen turkeys: As in paragraph (e)(3)(i) of this section; and for the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagrimitis* and *E. gallopavonis*..	Feed continuously as sole ration during the last 7 to 14 days prior to slaughter. See § 558.355(d)..	000986
(iv) 4.6 to 11.8 (5 to 13 ppm).	Monensin 54 to 90 ...	Finishing tom turkeys: As in paragraph (e)(3)(ii) of this section; and for the prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides*, *E. meleagrimitis* and *E. gallopavonis*..	Feed continuously as sole ration during the last 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality. See § 558.355(d)..	000986

[67 FR 71820, Dec. 3, 2002]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.500, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.515 Robenidine hydrochloride.

(a) *Approvals*. Type A medicated articles: 30 grams per pound to 046573 in § 510.600(c) of this chapter.

(b) *Special considerations*. Type C feed containing robenidine hydrochloride must be fed within 50 days from the date of manufacture. Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances*. See § 556.580 of this chapter.

(d) *Conditions of use*. It is used in feed for chickens as follows:

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
30 (0.0033 pct) ...	.....	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix*..	Feed continuously as sole ration. Do not feed to layers. Withdraw 5 days prior to slaughter..	046573
.....	Bacitracin (as bacitracin methylene disalicylate) 4 to 30.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix*. For increased rate of weight gain..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	046573
.....	Bacitracin (as bacitracin methylene disalicylate) 27 to 50.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix*. For improved feed efficiency..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	046573
	Bacitracin (as bacitracin methylene disalicylate) 50.	For broiler and fryer chickens: As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter..	046573

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
	Bacitracin (as bacitracin methylene disalicylate) 100 to 200.	For broiler and fryer chickens: As an aid in the control of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin..	To control a necrotic enteritis outbreak, start medication at first clinical signs of disease; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin methylene disalicylate to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter..	046573
.....	Bacitracin (as bacitracin methylene disalicylate) 50 and roxarsone 22.7 to 45.4.	For broiler chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. For increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed continuously as sole ration. Use as the sole source of organic arsenic; poultry should have access to water at all times; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	046573
.....	Bacitracin (as bacitracin methylene disalicylate) 100 to 200 and roxarsone 22.7 to 45.4.	For broiler chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. For increased rate of weight gain, improved feed efficiency, and improved pigmentation..	To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Use as the sole source of organic arsenic; poultry should have access to water at all times; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	046573
.....	Bacitracin (as bacitracin zinc) 4 to 30.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For increased rate of weight gain..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	046573 046573
.....	Bacitracin (as bacitracin zinc) 27 to 50.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For improved feed efficiency..	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter..	046573 046573
.....	Chlortetracycline 100 to 200.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline..	Feed continuously as sole ration up to 14 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter..	
.....	Chlortetracycline 200 to 400.	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline..	Feed continuously as sole ration up to 14 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter..	

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
.....	Chlortetracycline 500	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* As an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline..	Feed continuously as sole ration up to 5 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter..	046573
.....	Lincomycin 2	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For increase in rate of weight gain and improved feed efficiency..	Feed continuously as the sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter..	000009
.....	Oxytetracycline 400	For broiler chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For control of CRD and air sac infection caused by *Mycoplasma gallisepticum* and *E. coli* susceptible to oxytetracycline..	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days before slaughter..	066104
.....	Roxarsone 22.5 to 45.4 (0.005 percent).	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.* For increased rate of weight gain..	Feed continuously as the sole ration. Use as sole source of organic arsenic. Do not feed to layers. Withdraw 5 days prior to slaughter..	046573

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.515, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.530 Roxarsone.

(a) *Specifications.* Type A medicated articles containing 10, 20, 50, or 80 percent roxarsone.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 046573 for use of 10, 20, and 50 percent Type A medicated articles as in paragraph (d)(1)(i) of this section.

(2) No. 046573 for use of 10, 20, 50, and 80 percent Type A medicated articles as in paragraphs (d)(1) through (d)(3) of this section.

(c) *Related tolerances.* See § 556.60 of this chapter.

(d) *Conditions of use*—(1) *Chickens.* It is used in chicken feed as follows:

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 22.7 to 45.4		Growing chickens: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs.	046573
(ii) 22.7 to 45.4	Chlortetracycline 10 to 50	Growing chickens: As in paragraph (d)(1)(i) of this section.	As in paragraph (d)(1)(i) of this section. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(iii) 22.7 to 45.4	Chlortetracycline 100 to 200	Growing chickens: As in paragraph (d)(1)(i) of this section; and for control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	As in paragraph (d)(1)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(iv) 22.7 to 45.4	Chlortetracycline 200 to 400	Growing chickens: As in paragraph (d)(1)(i) of this section; and for control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	As in paragraph (d)(1)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(v) 22.7 to 45.4	Chlortetracycline 500	Growing chickens: As in paragraph (d)(1)(i) of this section; and for reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	As in paragraph (d)(1)(i) of this section except feed continuously for 5 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	

(2) *Turkeys.* It is used in turkey feed as follows:

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 22.7 to 45.4		Growing turkeys: For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in weakness or paralysis of the legs.	046573
(ii) 22.7 to 45.4	Chlortetracycline 10 to 50	Growing turkeys: As in paragraph (d)(2)(i) of this section.	As in paragraph (d)(2)(i) of this section. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(iii) 22.7 to 45.4	Chlortetracycline 200	Growing turkeys: As in paragraph (d)(2)(i) of this section; and for control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	As in paragraph (d)(2)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(iv) 22.7 to 45.4	Chlortetracycline 400	1. Growing turkeys: As in paragraph (d)(2)(i) of this section; and for control of hexamitiasis caused by *Hexamita meleagrides* susceptible to chlortetracycline. 2. Turkey poults not over 4 weeks of age: Reduction of mortality due to paratyphoid caused by *Salmonella typhimurium* susceptible to chlortetracycline.	As in paragraph (d)(2)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	
(v) 22.7 to 45.4	Chlortetracycline 25 mg/lb body weight daily	Growing turkeys: As in paragraph (d)(2)(i) of this section; and for control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.	As in paragraph (d)(2)(i) of this section except feed continuously for 7 to 14 days. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	

(3) *Swine*. It is used in swine feed as follows:

Roxarsone in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(i) 22.7 to 34.1		Growing and finishing swine: For increased rate of weight gain and improved feed efficiency.	Feed continuously throughout growing period; withdraw 5 days before slaughter; as sole source of organic arsenic.	046573
(ii) 22.7 to 34.1	Chlortetracycline 400 (to administer 10 mg/lb body weight)	Growing and finishing swine: As in paragraph (d)(3)(i) of this section; and for treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed for not more than 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic.	
(iii) 181.5		Growing and finishing swine: For the treatment of swine dysentery.	Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	046573
(iv) 181.5	Chlortetracycline 10 to 50	Growing and finishing swine: As in paragraph (d)(3)(i) of this section; and for treatment of swine dysentery.	Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	
(v) 181.5	Chlortetracycline 400 (to administer 10 mg/lb body weight)	Growing and finishing swine: As in paragraph (d)(3)(iii) of this section; and for treatment of bacterial enteritis caused by *E. coli* and *S. choleraesuis* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.	Feed for not more than 6 consecutive days; if improvement is not observed, consult a veterinarian; withdraw 5 days before slaughter; as a sole source of organic arsenic; animals must consume enough medicated feed to provide a therapeutic dose.	

(4) *Permitted combinations*. It may be used in accordance with this section in combination with:

(i) [Reserved]

(ii) Amprolium as in § 558.55.

(iii) Amprolium and ethopabate as in § 558.58.

(iv) Bacitracin methylene disalicylate as in § 558.76.

(v) Bacitracin zinc as in § 558.78.

(vi) Bambermycins and bambermycins plus certain anticoccidials as in § 558.95.

(vii) Chlortetracycline as in § 558.128.

(viii) Clopidol as in § 558.175.

(ix) Decoquinate alone or in combination as in § 558.195.

(x) Diclazuril alone or in combination as in § 558.198.

(xi) Halofuginone alone or in combination as in § 558.265.

(xii) Lasalocid alone or in combination as in § 558.311.

(xiii) Monensin alone or in combination as in § 558.355.

(xiv) Narasin alone or in combination as in § 558.363.

(xv) Nequinate as in § 558.365.

(xvi) Nicarbazin alone or in combination as in § 558.366.

(xvii) [Reserved]

(xviii) Penicillin and zoalene as in § 558.680.

(xix) Robenidine hydrochloride as in § 558.515.

(xx) Salinomycin alone or in combination as in § 558.550.

(xxi) Semduramicin alone or in combination as in § 558.555.

(xxii) Sulfadimethoxine, ormetoprim as in § 558.575.

(xxiii) Zoalene alone or in combination as in § 558.680.

[46 FR 52331, Oct. 27, 1981]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.530, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.550 Salinomycin.

(a) *Specifications.* Type A medicated articles containing 30 or 60 grams of salinomycin activity per pound (as salinomycin sodium biomass).

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) No. 046573 for use as in paragraph (d) of this section.

(2) No. 016592 for use as in paragraphs (d)(1)(i), (d)(1)(iii) through (d)(1)(xvi), (d)(1)(xxiii) and (d)(1)(xxiv), (d)(2)(i), (d)(3)(i), and (d)(4) of this section.

(3) No. 048164 for use as in paragraphs (d)(1)(xv) and (d)(1)(xvi) of this section.

(c) [Reserved]

(d) *Conditions of use.* (1) Broilers: It is used as follows:

(i)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(*c*) *Limitations.* Feed continuously as sole ration. Do not feed to layers. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses.

(ii)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and roxarsone 45.4 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone.

(*c*) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 011526 or 046573 in § 510.600(c) of this chapter.

(iii)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin methylene disalicylate 4 to 30 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* for incresed rate of weight gain and improved feed efficiency.

(*c*) *Limitation.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentially fed to adult turkeys or horses. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

(iv)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 45.4 grams and bacitracin methylene disalicylate 4 to 50 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain.

(*c*) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone and bacitracin as provided by No. 046573 in § 510.600(c) of this chapter.

(v)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams per ton with roxarsone 22.7 to 45.4 grams per ton.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimera tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima* and for improved feed efficiency.

(*c*) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidently fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(vi)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin methylene disalicylate 4 to 50 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for improved feed efficiency.

(*c*) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin MD as provided by No. 046573 in § 510.600(c) of this chapter.

(vii)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and bacitracin zinc 10 to 50 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain.

(*c*) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter.

(viii)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 45.4 grams and bacitracin zinc 4 to 50 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain and improved feed efficiency.

(*c*) *Limitations.* See paragraph (d)(1)(iv)(*c*) of this section.

(ix)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 34.1 grams and bacitracin zinc 10 to 50 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.

(*c*) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Withdraw 5 days before slaughter. Roxarsone as provided by No. 046573 and bacitracin as provided by No. 046573 in § 510.600(c) of this chapter.

(x)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and virginiamycin 5 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.

(*c*) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers or to chickens over 16 weeks of age. May be fatal if accidentally fed to adult turkeys or horses. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.

(xi)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and virginiamycin 5 to 15 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain.

(*c*) *Limitations.* See paragraph (d)(1)(x)(*c*) of this section.

(xii) (*a*) *Amount per ton.* Salinomycin 40 to 60 grams, virginiamycin 5 grams, and roxarsone 45.4 grams.

(*b*) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and for improved feed efficiency.

(*c*) *Limitations.* Feed continuously as sole ration. Withdraw 5 days prior to slaughter. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xiii)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and lincomycin 2 to 4 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria*

tenella, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* and for improved feed efficiency.

(*c*) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. Do not allow horses, adult turkeys, guinea pigs, rabbits, hamsters, or ruminants access to this feed. Ingestion by these species may result in severe gastrointestinal effects or may be fatal. Lincomycin hydrochloride monohydrate as provided by No. 000009 in § 510.600(c) of this chapter.

(xiv)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams, roxarsone 45.4 grams, and lincomycin 2 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and for improved feed efficiency.

(*c*) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. Drug overdose or lack of water may result in leg weakness. Do not feed to layers. Do not allow horses, adult turkeys, guinea pigs, rabbits, hamsters, or ruminants access to this feed. Ingestion by these species may result in severe gastrointestinal effects or may be fatal. Withdraw 5 days before slaughter. Lincomycin hydrochloride monohydrate as provided by No. 000009 in § 510.600(c) of this chapter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xv)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams, chlortetracycline 500 grams, and roxarsone 45.4 grams.

(*b*) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* which are more susceptible to roxarsone combined with salinomycin than to salinomycin alone, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

(*c*) *Limitations.* Do not feed to layers. In feeds containing 0.8 percent dietary calcium, not to be fed for more than 5 days. Not approved for use with pellet binders. Withdraw 5 days before slaughter. May be fatal if accidentally fed to adult turkeys or to horses. Chlortetracycline as provided by Nos. 046573 and 048164; roxarsone as provided by No. 046573; and salinomycin as provided by Nos. 046573 and 016592 in § 510.600(c) of this chapter.

(xvi)(*a*) *Amount per ton.* Salinomycin 40 to 60 grams and chlortetracycline 500 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E., necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

(*c*) *Limitations.* Do not feed to layers. In feeds containing 0.8 percent dietary calcium. Not to be fed for more than 5 days. Not approved for use with pellet binders. Withdraw 24 hours before slaughter. May be fatal if accidentally fed to adult turkeys or horses. Chlortetracycline as provided by Nos. 046573 and 048164; salinomycin as provided by Nos. 046573 and 016592 in § 510.600(c) of this chapter.

(xvii)(A) *Amount per ton.* Salinomycin 40 to 60 grams with roxarsone 34.1 or 45.4 grams and bacitracin methylene disalicylate 4 to 50 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain. Use of 34.1 or 45.4 grams per ton roxarsone is indicated to meet the *E. tenella* challenge which varies with environmental and management conditions.

(C) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to laying chickens. May be fatal if accidentally fed to adult turkeys or horses. Poultry should have access to drinking water at all times. Overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Salinomycin as provided by No. 046573 in § 510.600(c) of this chapter. Roxarsone and bacitracin as provided

by No. 046573 in § 510.600(c) of this chapter.

(xviii)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 50 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by Nos. 046573; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xix)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 100 to 200 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 046573; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(xx)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; and bacitracin methylene disalicylate, 50 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(C) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 046573; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) in this chapter.

(xxi)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; and bacitracin methylene disalicylate, 100 to 200 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(C) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 046573; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) in this chapter.

(xxii) *Amount per ton.* Salinomycin, 40 to 60 grams; plus tylosin, 4 to 50 grams.

(A) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration.

Do not feed to laying hens. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Salinomycin as provided by 046573; tylosin phosphate as provided by 000986 in § 510.600(c) of this chapter.

(xxiii) *Amount per ton.* Salinomycin, 40 to 60 grams; plus bambermycins, 1 to 3 grams.

(*a*) *Indications for use.* Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; and for improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens; not approved for use with pellet binders; may be fatal if accidentally fed to adult turkeys or horses. Salinomycin as provided by Nos. 046573 and 016592; bambermycins by No. 016592 in § 510.600(c) of this chapter.

(xxiv) *Amount per ton.* Salinomycin, 40 to 60 grams; plus bambermycins, 1 to 2 grams; plus roxarsone, 45.4 grams.

(*a*) *Indications for use.* Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone; and for improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration. Do not feed to laying chickens; as sole source or organic arsenic; withdraw 5 days before slaughter; not approved for use with pellet binders; may be fatal if accidentally fed to adult turkeys or horses; Salinomycin as provided by Nos. 046573and 016592; bambermycins by No. 016592; roxarsone by No. 046573 in § 510.600(c) of this chapter.

(2) *Quail*—(i)(*a*) *Amount per ton.* Salinomycin 50 grams.

(*b*) *Indications for use.* For the prevention of coccidiosis caused by *E. dispersa* and *E. lettyae*.

(*c*) *Limitations.* Feed continuously as sole ration. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses.

(ii) [Reserved]

(3) *Roaster and replacement (breeder and layer) chickens*: It is used as follows:

(i)(A) *Amount per ton.* Salinomycin 40 to 60 grams.

(B) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(C) *Limitations.* Feed continuously as sole ration. Do not feed to laying hens producing eggs for human consumption. Not approved for use with pellet binders. May be fatal if accidentally fed to horses or adult turkeys.

(ii) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylene disalicylate, 4 to 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 046573; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylene disalicylate, 50 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 046573; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(iv)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 50 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an

aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 046573; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c).

(v) *Amount per ton.* Salinomycin, 40 to 60 grams, and bacitracin methylene disalicylate, 100 to 200 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

(B) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). Discontinue use prior to sexual maturity. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by 046573; bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(vi)(A) *Amount per ton.* Salinomycin, 40 to 60 grams; bacitracin methylene disalicylate, 100 to 200 grams; and roxarsone, 22.7 to 45.4 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(C) *Limitations.* Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Discontinue use prior to sexual maturity. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 046573; bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c).

(vii) *Amount per ton.* Salinomycin, 40 to 60 grams; and roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*,*E. necatrix*,*E. acervulina*,*E. brunetti*,*E. mivati*, and*E. maxima*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Feed continuously as sole ration. Discontinue use prior to sexual maturity. Do not feed to laying chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. May be fatal if fed to adult turkeys or to horses. Withdraw 5 days before slaughter. Salinomycin as provided by No. 046573 and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.

(4) *Chickens*: It is used in chicken feed as follows:

(i) *Amount per ton.* Salinomycin, 40 to 60 grams; plus oxytetracycline, 500 grams.

(*a*) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; and for reduction of mortality due to air sacculitis (air-sac-infection) caused by *Escherichia coli* susceptible to oxytetracycline.

(*b*) *Limitations.* Feed continuously for 5 days; do not feed to chickens producing eggs for human consumption; withdraw 24 hours before slaughter; in low calcium feeds withdraw 3 d before slaughter. Salinomycin as provided by Nos. 046573 and 016592; oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter.

(ii) [Reserved]

[48 FR 30616, July 5, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.550, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.555 Semduramicin.

(a) *Specifications.* Type A medicated article containing:

(1) 22.7 grams (g) per pound (lb) (50 g/kilogram (kg)) semduramicin (as semduramicin sodium).

(2) 22.7 g/lb (50 g/kg) semduramicin (as semduramicin sodium biomass).

(b) *Approvals.* See No. 066104 in § 510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (d) of this section; for use of product described in paragraph (a)(2) as in paragraph (e) of this section.

(c) *Related tolerances.* See § 556.597 of this chapter.

(d) *Conditions of use in chickens.* It is used in chicken feed as follows:

Semduramicin in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(1) 22.7 (25 ppm)		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati*/*E. mitis, E. necatrix*, and *E. tenella*.	Do not feed to laying hens.	066104
(2) 22.7	Bacitracin methylene disalicylate 10 to 50	Broiler chickens: As in paragraph (d)(1) of this section; for improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying hens. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.	066104
(3) 22.7	Bacitracin methylene disalicylate 10 to 50 plus roxarsone 45.4	Broiler chickens: As in paragraph (d)(4) of this section; for improved feed efficiency.	Feed continuously as sole ration. Use feed within 2 weeks of production. Do not feed to laying hens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Bacitracin methylene disalicylate and roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.	066104
(4) 22.7	Roxarsone 45.4	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati*/*E. mitis, E. necatrix*, and *E. tenella*, including some field strains of *E. tenella* that are more susceptible to semduramicin combined with roxarsone than semduramicin alone.	Feed continuously as sole ration. For broiler chickens only. Do not feed to laying hens. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Roxarsone as provided by No. 046573 in § 510.600(c) of this chapter.	066104

Semduramicin in grams per ton	Combinations in grams per ton	Indications for use	Limitations	Sponsor
(5) 22.7	Virginiamycin 5	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying hens. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(6) 22.7	Virginiamycin 5 to 15	Broiler chickens: As in paragraph (d)(1) of this section; for increased rate of weight gain.	Feed continuously as sole ration. Do not feed to laying hens. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(7) 22.7	Virginiamycin 20	Broiler chickens: As in paragraph (d)(1) of this section; for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin.	Feed continuously as sole ration. Do not feed to laying hens. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(8) 22.7	Virginiamycin 20 plus roxarsone 22.7 to 45.4	Broiler chickens: As in paragraph (d)(1) of this section; for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; for increased rate of weight gain and improved feed efficiency; and for improved pigmentation.	Feed continuously as sole ration throughout growing period. Do not feed to laying hens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water may result in leg weakness. Roxarsone as in § 558.530(b)(1) of this chapter provided by No. 046573 in § 510.600(c) of this chapter; semduramicin and virginiamycin as provided by No. 066104.	066104

(e) *Conditions of use in chickens.* It is used in chicken feed as follows:

Semduramicin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 22.7 (25 ppm)		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix, and E. mitis.*	Do not feed to laying hens.	066104
(2) 22.7	Virginiamycin 5	Broiler chickens: As in paragraph (e)(1) of this section; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Virginiamycin provided by No. 066104 in § 510.600(c) of this chapter.	066104
(3) 22.7	Virginiamycin 5 to 15	Broiler chickens: As in paragraph (e)(1) of this section; for increased rate of weight gain.	Feed continuously as sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Virginiamycin provided by No. 066104 in § 510.600(c) of this chapter.	066104
(4) 22.7	Virginiamycin 20	Broiler chickens: As in paragraph (e)(1) of this section; for prevention of necrotic enteritis caused by *C. perfringens* susceptible to virginiamycin.	Feed continuously as sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Virginiamycin provided by No. 066104 in § 510.600(c) of this chapter.	066104

[59 FR 17477, Apr. 13, 1994, as amended at 60 FR 57928, Nov. 24, 1995; 61 FR 29481, June 11, 1996; 61 FR 43451, Aug. 23, 1996; 61 FR 66584, Dec. 18, 1996; 62 FR 66985, Dec. 23, 1997; 64 FR 48296, Sept. 3, 1999; 66 FR 47964, Sept. 17, 2001; 69 FR 13221, Mar. 22, 2004; 70 FR 41961, July 21, 2005; 73 FR 812, Jan. 4, 2008; 74 FR 41631, Aug. 18, 2009]

§ 558.575 Sulfadimethoxine, ormetoprim.

(a) *Approvals.* Type A medicated articles to sponsors as identified in § 510.600(c) of this chapter for uses as in paragraph (d) of this section as follows:

(1) 25 percent sufadimethoxine and 15 percent ormetoprim to 046573 for use for poultry as in paragraphs (d)(1), (d)(2), (d)(3), (d)(4), and (d)(7) of this section.

(2) 25 percent sulfadimethoxine and 5 percent ormetoprim to No. 015331 for use for fish as in paragraphs (d)(5) and (d)(6) of this section.

(b) *Related tolerances.* See §§ 556.490 and 556.640 of this chapter.

(c) [Reserved]

(d) *Conditions -of use.* It is used in feeds for animals as follows:

(1) *Broiler chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(*b*) *Limitations.* Feed as sole ration; withdraw 5 days before slaughter.

(ii) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent) plus roxarsone, 22.7 grams (0.0025 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli*, (colibacillosis); and *P. multocida* (fowl cholera); growth promotion and feed efficiency; improving pigmentation.

(*b*) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) *Replacement chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and bacterial infections due to *H. galmaxima*, and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).

(iii) *Limitations.* Feed as a sole ration; do not feed to chickens over 16 weeks (112 days) of age; withdraw 5 days before slaughter.

(3) *Turkeys*—(i) *Amount per ton.* Sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides*, *E. gallopavonis*, and *E. meleagrimitis* and bacterial infection due to *P. multocida* (fowl cholera).

(iii) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 5 days before slaughter.

(4) *Ducks*—(i) *Amount per ton.* Sulfadimethoxine, 227 grams (0.025 percent) plus ormetoprim, 136.2 grams (0.015 percent).

(*a*) *Indications for use.* As an aid in the control of bacterial infections due to *P. multocida* (fowl cholera) in ducks, including breeding ducks.

(*b*) *Limitations.* Feed as sole ration for 7 days; withdraw 5 days before slaughter; medication should be started at the first signs of infection; do not feed to ducks producing eggs for food.

(ii) *Amount per ton.* Sulfadimethoxine, 454 grams (0.05 percent) plus ormetoprim, 272.4 grams (0.03 percent).

(*a*) *Indications for use.* As an aid in the control of bacterial infections due to *E. coli*, *Riemerella anatipestifer*, and severe challenge of *P. multocida* (fowl cholera) in ducks.

(*b*) *Limitations.* Feed as a sole ration for 7 days; withdraw 5 days before slaughter; medication should be started at the first signs of infection; not for breeding ducks; do not feed to ducks producing eggs for food.

(5) *Salmonids*—(i) *Amount.* 50 milligrams of active ingredients per kilogram of body weight per day.

(ii) *Indications of use.* For the control of furunculosis in salmonids (trout and salmon) caused by *Aeromonas salmonicida* strains susceptible to sulfadimethoxine and ormetoprim combination.

(iii) *Limitations.* Administer for 5 consecutive days; withdraw 42 days before release as stocker fish or slaughter.

(6) *Catfish*—(i) *Amount.* 50 milligrams of active ingredients per kilogram of body weight per day.

(ii) *Indications for use.* For control of enteric septicemia of catfish caused by *Edwardsiella ictaluri* strains susceptible to sulfadimethoxine and ormetoprim combination.

(iii) *Limitations.* Administer for 5 consecutive days; withdraw 3 days before slaughter or release as stocker fish.

(7) *Chukar partridges*—(i) *Amount per ton.* Sulfadimethoxine 113.5 grams (0.0125 percent) plus ormetoprim 68.1 grams (0.0075 percent).

(ii) *Indications for use.* For prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis.*

(iii) *Limitations.* Feed continuously to young birds up to 8 weeks of age as sole ration.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 13550, Mar. 11, 1977; 49 FR 33442, Aug. 23, 1984; 49 FR 46371, Nov. 26, 1984; 51 FR 7400, Mar. 3, 1986; 51 FR 18884, May 23, 1986; 52 FR 2686, Jan. 26, 1987; 54 FR 1686, Jan. 17, 1989; 63 FR 27846, May 21, 1998; 64 FR 26672, May 17, 1999; 64 FR 43910, Aug. 12, 1999; 66 FR 46707, Sept. 7, 2001; 70 FR 52292, Sept. 2, 2005]

§ 558.582 Sulfamerazine.

(a) *Approvals.* Type A medicated articles: 99 percent to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.660 of this chapter.

(c) *Conditions of use.* It is used in fish feed for rainbow trout, brook trout, and brown trout as follows:

(1) *Amount.* 10 grams of sulfamerazine per 100 pounds of fish per day.

(2) *Indications for use.* Control of furunculosis.

(3) *Limitations.* Treat for not more than 14 days; do not treat within 3 weeks of marketing or stocking in stream open to fishing.

[41 FR 11005, Mar. 15, 1976, as amended at 51 FR 7400, Mar. 3, 1986; 61 FR 18082, Apr. 24, 1996; 63 FR 27846, May 21, 1998; 66 FR 46707, Sept. 7, 2001]

§ 558.586 Sulfaquinoxaline.

(a) *Specifications.* Type A medicated articles containing 40 percent sulfaquinoxaline.

(b) *Approvals.* See No. 059130 in § 510.600(c) of this chapter.

(c) *Special considerations.* (1) For control of outbreaks of disease, medication should be initiated as soon as the diagnosis is determined. Medicated chickens, turkeys, and rabbits must actually consume enough medicated feed which provides a recommended dose of approximately 3.5 to 60 milligrams per pound per day in chickens, 2.5 to 100 milligrams per pound per day in turkeys, and 2.8 to 68 milligrams per pound per day in rabbits depending upon age and class of animal, ambient temperature, and other factors. Consult a veterinarian or poultry pathologist for diagnosis.

(2) [Reserved]

(d) *Conditions of use.* It is used as follows:

(1) *Chickens*—(i) *Amount.* 0.015 percent.

(*a*) *Indications for use.* As an aid in preventing outbreaks of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima,* and *E. brunetti* under average conditions of exposure.

(*b*) *Limitations.* Feed continuously from the time birds are placed on litter and continue past the age when coccidiosis is ordinarily a hazard. If death losses exceed 0.5 percent in a 2-day period, obtain a laboratory diagnosis. If coccidiosis is the cause, use the sulfaquinoxaline levels recommended for control of outbreaks, returning to the original dosage schedule after the outbreak has subsided. Losses may result from intercurrent disease, other conditions affecting drug intake, or variant strains of coccidia species which can contribute to the virulence of coccidiosis under field conditions. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.

(ii) *Amount.* 0.0175 percent.

(*a*) *Indications for use.* As an aid in preventing outbreaks of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, and *E. brunetti* where excessive exposure to coccidia is increased due to overcrowding or other management factors.

(*b*) *Limitations.* Feed continuously from the time birds are placed on litter and continue past the age when coccidiosis is ordinarily a hazard. If death losses exceed 0.5 percent in a 2-day period, obtain a laboratory diagnosis. If coccidiosis is the cause, use the sulfaquinoxaline levels recommended for control of outbreaks, returning to the original dosage schedule after the outbreak has subsided. Losses may result from intercurrent disease, other conditions affecting drug intake, or variant strains of coccidia species which can contribute to the virulence of coccidiosis under field conditions. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.

(iii) *Amount.* 0.1 to 0.05 percent.

(*a*) *Indications for use.* As an aid in controlling outbreaks of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, and *E. brunetti.*

(*b*) *Limitations.* Feed at 0.1 percent level for first 48 to 72 hours. Skip 3 days; 0.05 percent for 2 days, skip 3 days; 0.05 percent for 2 days. If bloody droppings recur, give 0.05 percent for another 2 days. Do not treat chickens within 10 days of slaughter. Do not medicate chickens producing eggs for human consumption.

(2) *Turkeys*—(i) *Amount.* 0.0175 percent.

(*a*) *Indications for use.* As an aid in preventing outbreaks of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides.*

(*b*) *Limitations.* Feed 0.0175 percent continuously during time birds are closely confined. May be continued for week to 10 days after flock is transferred to range to reduce danger of an outbreak following moving of the flock. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption.

(ii) *Amount.* 0.05 percent.

(*a*) *Indications for use.* As an aid in controlling outbreaks of coccidiosis caused by *Eimeria meleagrimitis*, and *E. adenoeides.*

(*b*) *Limitations.* Feed 0.05 percent for 2 days. Follow with 3 days on regular feed and 2 more days on 0.05 percent sulfaquinoxaline feed. Again follow with 3 days on regular feed and 2 more days on 0.05 percent sulfaquinoxaline feed. Continue this schedule if necessary till all signs of the outbreaks have subsided. Do not treat turkeys within 10 days of slaughter. Do not medicate turkeys producing eggs for human consumption.

(3) *Chickens and turkeys*—(i) *Amount.* 0.05 or 0.1 percent.

(*a*) *Indications for use.* As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfaquinoxaline and fowl typhoid caused by *Salmonella gallinarum* susceptible to sulfaquinoxaline.

(*b*) *Limitations.* Feed 0.1 percent for 48 to 72 hours. Mortality should be brought under control. After medication, move birds to clean ground or to a clean house. If disease recurs, use 0.05 percent in feed again for 2 days. Do not treat chickens or turkeys within 10 days of slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption.

(ii) [Reserved]

(4) *Rabbits*—(i) *Amount.* 0.025 percent.

$(a) *Indications for use.* As an aid in preventing coccidiosis caused by *Eimeria stiedae.*

$(b) *Limitations.* Treatment to be started after weaning. Feed continuously for 30 days or feed medicated feed for 2 days out of every week until marketing. Do not treat within 10 days of slaughter.

(ii) *Amount.* 0.1 percent.

(*a*) *Indications for use.* As an aid in controlling outbreaks of coccidiosis caused by *Eimeria stiedae.*

$(b) *Limitations.* Feed for 2 weeks. Do not treat within 10 days of slaughter.

[48 FR 3965, Jan. 28, 1983, as amended at 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 29843, July 23, 1990; 59 FR 33197, June 28, 1994; 69 FR 60547, Oct. 12, 2004]

§ 558.600 Tiamulin.

(a) *Specifications.* Type A article containing 5, 10, or 113.4 grams of tiamulin

(as tiamulin hydrogen fumarate) per pound.

(b) *Approvals*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.738 of this chapter.

(d) *Special considerations*—(1) Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(2) The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

(3) Use as sole source of tiamulin.

(e) *Conditions of use*—(1) *Swine*. It is used as follows:

Tiamulin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10		For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Not for use in swine weighing over 250 pounds.	058198
(ii) 35		1. For control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.	Feed continuously as sole ration on premises with a history of swine dysentery but where signs of disease have not yet occurred or following approved treatment of disease. Withdraw 2 days before slaughter.	058198
		2. For control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*.	Feed continuously as the sole ration for not less than 10 days. Withdraw 2 days before slaughter.	058198
(iii) 35	Chlortetracycline, approximately 400 (varying with body weight and feed consumption to provide 10 milligrams of chlortetracycline per pound of body weight daily).	For treatment of swine bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline, and control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.	Feed continuously as sole ration for 14 days. Use as only source of chlortetracycline. Withdraw 2 days before slaughter. As chlortetracycline calcium complex, Type A medicated articles containing the equivalent of 50 to 100 grams per pound of chlortetracycline hydrochloride provided by 046573 and 048164 in § 510.600(c) of this chapter.	048164, 058198
(iv) 200		For treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.	Feed continuously as the sole feed for 14 consecutive days. Withdraw feed 7 days before slaughter.	058198

(2) [Reserved]

[67 FR 7268, Feb. 19, 2002, as amended at 69 FR 62407, Oct. 26, 2004; 70 FR 75018, Dec. 19, 2005; 74 FR 6, Jan. 2, 2009]

§ 558.615 Thiabendazole.

(a) *Approvals*. Dry Type A medicated articles: 22, 44.1, 66.1, and 88.2 percent to 050604 in § 510.600(c) of this chapter. The 66.1 percent Type A is solely for the manufacture of cane molasses liquid Type B feed which is mixed in dry feeds. The 88.2 percent Type A is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

(b) *Special considerations*. Do not use in Type B or Type C medicated feed containing bentonite.

(c) *Related tolerances*. See § 556.730 of this chapter.

(d) *Conditions of use*. It is used in feed for animals as follows:

(1) *Cattle*—(i) *Amount*. 3 grams per 100 lb. body weight.

(*a*) *Indications for use*. Control of infections of gastrointestinal roundworms (*Trichostrongylus spp.*, *Haemonchus spp.*, *Ostertagia spp.*,

Nematodirus spp., Oesophagostomum radiatum).

(*b*) *Limitations.* Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount.* 5 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*); control of infections of *Cooperia spp.*

(*b*) *Limitations.* 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Goats*—(i) *Amount.* 3 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*).

(iii) *Limitations.* 3 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(3) *Sheep and goats*—(i) *Amount.* 2 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp.; Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of *T. colubriformis* and *axei*, *Ostertagia spp., Nematodirus spp., Strongyloides spp.;* less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*).

(iii) *Limitations.* Use 2 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(4) *For swine*—(i) *Amount.* 45.4–908 grams per ton (0.005–0.1 percent).

(ii) *Indications for use.* Aid in the prevention of infections of large roundworms (genus *Ascaris*).

(iii) *Limitations.* Administer continuously feed containing 0.05–0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005–0.02 percent thiabendazole per ton for 8–14 weeks; do not treat animals within 30 days of slaughter.

(5) *Pheasants*—(i) *Amount.* 454 grams per ton (0.05 percent) continuously for 2 weeks (14 days).

(ii) *Indications for use.* For the treatment of gapeworms (*Syngamus trachea*) in pheasants.

(iii) *Limitations.* Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data are not available on use in breeding animals.

[40 FR 13959, Mar. 27, 1975, as amended at 47 FR 49641, Nov. 2, 1982; 49 FR 29958, July 25, 1984; 51 FR 7400, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 62 FR 63271, Nov. 28, 1997]

§ 558.618 Tilmicosin.

(a) *Specifications.* Type A medicated article containing 90.7 grams (g) per pound tilmicosin as tilmicosin phosphate (200 g per kilogram).

(b) *Approvals. See* No. 000986 in § 510.600(c) of this chapter.

(c) *Special considerations*—(1) Tilmicosin medicated feeds are restricted to use under a veterinary feed directive (VFD). See § 558.6 of this chapter for required label statements and other limitations.

(2) VFDs for tilmicosin phosphate shall not be refilled.

(3) Labeling of tilmicosin Type B or Type C medicated feeds must bear the following warnings:

(i) Do not allow horses or other equines access to feeds containing tilmicosin.

(ii) Use of antibacterial drugs in the absence of a susceptible bacterial infection is unlikely to provide benefit to treated animals and may increase the risk of the development of drug-resistant pathogenic bacteria.

(4) Special considerations for use of tilmicosin medicated swine feeds include the following:

(i) The expiration date of VFDs for tilmicosin must not exceed 90 days from the time of issuance.

(ii) Labeling of tilmicosin Type B or Type C medicated feeds for swine must bear the following warning: ''Do not use in any feeds containing bentonite. Bentonite in feeds may affect the efficacy of tilmicosin.''

(iii) Feed containing tilmicosin shall not be fed to pigs for more than 21 days during each phase of production without ceasing administration for reevaluation of antimicrobial use by a licensed veterinarian before reinitiating a further course of therapy with an appropriate antimicrobial.

(5) Special consideration for use of tilmicosin medicated cattle feeds include the following:

(i) The expiration date of VFDs for cattle must not exceed 45 days from the time of issuance.

(ii) Labeling of tilmicosin Type B or Type C medicated feeds for cattle must bear the following warning: ''Do not use in any feeds containing bentonite, cottonseed meal, or cottonseed hulls. Bentonite, cottonseed meal, or cottonseed hulls in feeds may affect the efficacy of tilmicosin.''

(iii) To assure both food safety and responsible use in cattle, administration of feed containing tilmicosin to cattle experiencing an outbreak of BRD must be initiated during the first 45 days of the production period, shall not exceed a single 14-consecutive-day treatment, should not occur concurrent with or following administration of an injectable macrolide, and should not occur within 3 days following administration of a nonmacrolide injectable BRD therapy. Tilmicosin medicated feed treatment has not been evaluated in cattle with severe clinical disease. Cattle with severe clinical illness should be evaluated for individual treatment with an alternative nonmacrolide therapy.

(d) *Related tolerances.* See § 556.735 of this chapter.

(e) *Conditions of use.* It is used in feed as follows:

Tilmicosin phosphate in grams/ton	Indications for use	Limitations	Sponsor
(1) 181 to 363	Swine: For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida.*	Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an anticipated disease outbreak. The safety of tilmicosin has not been established in male swine intended for breeding purposes. Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this drug product.	000986
(2) 568 to 757	Cattle: For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of beef and nonlactating dairy cattle, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 milligrams/kilogram/head/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product..	000986

[61 FR 68148, Dec. 27, 1996; 62 FR 15391, Apr. 1, 1997, as amended at 64 FR 13679, Mar. 22, 1999; 65 FR 76930, Dec. 8, 2000; 67 FR 21997, May 2, 2002; 69 FR 78306, Dec. 30, 2004; 76 FR 76894, Dec. 9, 2011]

§ 558.625 Tylosin.

(a) *Specifications.* Type A medicated articles containing tylosin phosphate.

(b) *Approvals.* Type A medicated article levels of tylosin granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section.

(1) To 000986: 10, 40, 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(2)–(4) [Reserved]

(5) To No. 051311: 0.4, 0.8, 1, and 8 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(6)–(8) [Reserved]

(9)–(13)[Reserved]

(14) To 016968: 1, 2, 4, 8, and 10 grams per pound, paragraphs (f)(1) (i), (iii), (iv), and (vi) of this section; 20, 25, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(15)–(24) [Reserved]

(25) To 066104: 4, 8, and 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 20 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(26)–(32) [Reserved]

(33) To 034936: 0.8 and 2 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 4, 8, and 10 grams per pound, paragraphs (f)(1)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section; 100 grams per pound, paragraphs (f)(1) (i), (ii), (iii), (iv), and (vi) of this section.

(34) [Reserved]

(35) To 039741: 2 and 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section.

(36)–(38) [Reserved]

(39) To 061623: 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section.

(40) To 035955: 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section.

(41)–(47) [Reserved]

(48) To 017790: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(49)–(53) [Reserved]

(54) To 046573: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(55)–(56) [Reserved]

(57) To 028459: 0.4 and 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(58)–(62) [Reserved]

(63) To 046987: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(64)–(65) [Reserved]

(66) To 024174: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(67)–(76) [Reserved]

(77) To 050639: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(78) To 050972: 0.36, 0.4, 0.72, and 0.8 gram per pound, paragraph (f)(1)(vi)(*a*) of this section; 1 gram per pound, paragraphs (f)(1)(vi) (*a*), (*b*), and (*d*) of this section.

(79)–(80) [Reserved]

(81)–(82) [Reserved]

(83) To 046573: 5-, 10-, 20-, and 40-grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(84) [Reserved]

(85) To 047126: 10, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(86)–(88) [Reserved]

(89) To 048164: 5, 10, 20, and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.

(c) *Special considerations.* (1) Type C medicated feeds for cattle may be manufactured from tylosin liquid Type B medicated feeds which have a pH between 4.5 and 6.0 and which bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the

top. Agitate daily as described even when not used.

(2) Tylosin liquid Type B medicated feeds used to make Type C medicated feeds for cattle may be manufactured from tylosin Type A medicated articles according to the following mixing directions:

(i) [Reserved]

(ii) Maintain a pH between 4.5 and 6.0.

(3) Tylosin liquid Type B medicated feeds must bear an expiration date of 31 days after the date of manufacture.

(d) [Reserved]

(e) *Related tolerances.* See § 556.740 of this chapter.

(f) *Conditions of use.* (1) It is used in animal feeds as follows:

(i) *For beef cattle*—(*a*) *Amount per ton.* 8–10 grams.

(*b*) *Indications for use.* For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes.*

(*c*) *Limitations.* As tylosin phosphate; each animal must receive not more than 90 milligrams per day and not less than 60 milligrams per day; feed continuously as sole ration.

(ii) *Broiler chickens*—(*a*) *Amount per ton.* Tylosin, 800–1000 grams.

(*b*) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(*c*) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24–48 hours at 3 to 5 weeks of age.

(iii) *Chickens*—(*a*) *Amount per ton.* Tylosin, 4–50 grams.

(*1*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*2*) *Limitations.* As tylosin phosphate.

(iv) *Laying chickens*—(*a*) *Amount per ton.* Tylosin, 20–50 grams.

(*b*) *Indications for use.* For improved feed efficiency.

(*c*) *Limitations.* As tylosin phosphate.

(v) *Replacement chickens*—(*a*) *Amount per ton.* Tylosin, 1,000 grams.

(*b*) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(*c*) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age.

(vi) *Swine*—(*a*) *Amount per ton.* Tylosin, 10–100 grams.

(*1*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*2*) *Limitations.* As tylosin phosphate; continuous use as follows: *Grams per ton:* 20–100, prestarter or starter; 20–40, grower; 10–20, finisher.

(*b*) *Amount per ton.* Tylosin, 40 or 100 grams.

(*1*) *Indications for use.* For control of swine dysentery associated with *Brachyspira hyodysenteriae*, and for control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis.*

(*2*) *Limitations.* Use 100 grams per ton for at least 3 weeks followed by 40 grams per ton until market weight; as tylosin phosphate.

(*c*) *Amount per ton.* Tylosin, 40–100 grams.

(*1*) *Indications for use.* For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* and for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis.*

(*2*) *Limitations.* Administer as tylosin phosphate in feed for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water as in § 520.2640(d)(3) of this chapter.

(*d*) *Amount per ton.* Tylosin, 100 grams.

(*1*) *Indications for use.* Maintaining weight gains and feed efficiency in presence of atrophic rhinitis.

(*2*) *Limitations.* As tylosin phosphate.

(vi) Pyrantel tartrate in accordance with § 558.485.

(*e*) *Amount per ton.* Tylosin 100 grams.

(*1*) *Indications for use.* For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis.*

(*2*) *Limitations.* As tylosin phosphate, administer for 21 days.

(2) Tylosin may also be used in combination with:

(i) Decoquinate and monensin as in § 558.195.

(ii) Hygromycin B as in § 558.274.

(iii) Melengestrol acetate alone or in combination with certain ionophores as in § 558.342.

(iv) Monensin as in § 558.355.

(v) Narasin as in § 558.363.

(vi) Pyrantel tartrate as in § 558.485.

(vii) Ractopamine alone or in combination as in § 558.500.

(viii) Salinomycin as in § 558.550.

(ix) Zilpaterol alone or in combination as in § 558.665.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.625, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.630 Tylosin and sulfamethazine.

(a) *Specifications*. Type A medicated articles containing equal amounts of tylosin phosphate and sulfamethazine, available in concentrations of 4, 5, 10, 20, or 40 grams each, per pound.

(b) *Approvals*. See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000986: 10 or 40 grams per pound each for use as in paragraph (e)(2)(i) of this section.

(2) [Reserved]

(3) No. 051311: 40 grams per pound each for use as in paragraph (e)(2)(ii) of this section.

(4)–(5) [Reserved]

(6) No. 000986: 40 grams per pound each for use as in paragraph (e)(2)(iii) of this section.

(c) *Special considerations*. Labeling shall bear the statement: ''Do not use in medicated feeds containing in excess of 2% bentonite.''

(d) *Related tolerances*. See §§ 556.670 and 556.740 of this chapter.

(e) *Conditions of use*. It is used in feed for swine as follows:

(1) *Amount per ton*. 100 grams tylosin and 100 grams sulfamethazine.

(2) *Indications for use*–(i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E *Streptococci*. Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.

(ii) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogenes*).

(iii) For maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhinitis; prevention of swine dysentery associated with *Brachyspira hyodysenteriae*; and control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Arcanobacterium pyogenes*).

(3) *Limitations*. Withdraw 15 days before swine are slaughtered.

[73 FR 34185, June 17, 2008, as amended at 73 FR 35341, June 23, 2008; 75 FR 55677, Sept. 14, 2010; 76 FR 17778, Mar. 31, 2011; 77 FR 4897, Feb. 1, 2012]

§ 558.635 Virginiamycin.

(a) *Approvals*. Type A medicated articles. (1) 1.1 percent activity (5 grams per pound), 2.2 percent activity (10 grams per pound), 4.4 percent activity (20 grams per pound), 11 percent activity (50 grams per pound), and 50 percent activity (227 grams per pound) used as in paragraph (d) of this section; and 30 percent activity (136.2 grams per pound) for the manufacture of Type C medicated feed for cattle used as in paragraph (d)(3); to 066104 in § 510.600(c) of this chapter.

(2) 2.2 percent activity (10 grams per pound) to 046573, 016968, and 017790 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(iv) and (d)(1)(v) of this section.

(b) *Related tolerances*. See § 556.750 of this chapter.

(c) *Special considerations*. (1) Not for use in breeding swine over 120 pounds.

(2) Dilute Type A article with at least 10 pounds of a feed ingredient prior to final mixing in 1 ton of Type C feed.

(d) *Conditions of use*—(1) *Swine*. It is used as follows:

(i) 100 grams per ton for 2 weeks, for treatment of swine dysentery in nonbreeding swine over 120 pounds.

(ii) 100 grams per ton for 2 weeks, 50 grams per ton thereafter, for treatment and control of swine dysentery in swine up to 120 pounds.

(iii) 25 grams per ton, as an aid in control of dysentery in swine up to 120 pounds. For use in animals or on premises with a history of swine dysentery but where symptoms have not yet occurred.

(iv) 10 grams per ton from weaning up to 120 pounds for increased rate of weight gain and improved feed efficiency, followed by 5 grams per ton to market weight for increased rate of weight gain and improved feed efficiency. For continuous use from weaning to market weight.

(v) 10 grams per ton from weaning up to 120 pounds for increased rate of weight gain and improved feed efficiency, followed by 5 to 10 grams per ton to market weight for increased rate of weight gain. For continuous use from weaning to market weight.

(2) *Poultry*. It is used as follows:

(i) 5 to 15 grams per ton for increased rate of weight gain, for use in broiler chickens, not for use in layers.

(ii) 5 grams per ton for increased rate of weight gain and improved feed efficiency in broiler chickens, not for use in layers.

(iii) 20 grams per ton for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin in broiler chickens; not for use in layers.

(iv) 10 to 20 grams per ton for increased rate of weight gain and improved feed efficiency in growing turkeys.

(3) *Cattle*. It is used as follows:

(i) 16.0 to 22.5 grams per ton to provide 100 to 340 milligrams per head per day for increased rate of weight gain.

(ii) 13.5 to 16.0 grams per ton to provide 85 to 240 milligrams per head per day for reduction of incidence of liver abscesses.

(iii) 11.0 to 16.0 grams per ton to provide 70 to 240 milligrams per head per day for improved feed efficiency.

(iv) Feed continuously as sole ration to cattle fed in confinement for slaughter. Not for use in animals intended for breeding.

(4) Virginiamycin may be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Diclazuril as in § 558.198.

(iii) Halofuginone as in § 558.265.

(iv) Lasalocid as in § 558.311.

(v) Monensin alone or with roxarsone as in § 558.355.

(vi) Salinomycin alone or with roxarsone as in § 558.550.

(vii) Semduramicin alone or with roxarsone as in § 558.555.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.635, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 558.665 Zilpaterol.

(a) *Specifications*. Type A medicated articles containing 21.77 grams (g) zilpaterol hydrochloride per pound.

(b) *Approvals*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Tolerances*. See § 556.765 of this chapter.

(d)*Special considerations*—(1) Labeling of Type B and Type C cattle feeds shall bear the following:

(i) Do not allow horses or other equines access to feed containing zilpaterol.

(ii) Not for use in animals intended for breeding.

(iii) Do not use in veal calves.

(2) Type B Liquid Feeds can be manufactured containing 68 to 680 g zilpaterol hydrochloride/ton. The liquid Type B feeds must be maintained at a pH of 3.8 to 7.5. For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used. For liquid feeds stored in mechanical, air or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(e) *Conditions of use in cattle.* It is administered in feed as follows:

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 6.8 to provide 60 to 90 mg/head/day		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.	Feed continuously as the sole ration during the last 20 to 40 days on feed. Withdrawal period: 3 days.	000061
(2) 6.8 to provide 60 to 90 mg/head/day	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(1) of this section; and for suppression of estrus (heat).	As in paragraph (e)(1) of this section; see paragraph §§ 558.342(d) of this chapter. Melengestrol acetate as provided by Nos. 000009 or 021641 in § 510.600(c) of this chapter.	000061 021641
(3) 6.8 to provide 60 to 90 mg/head/day	Monensin 10 to 40	Cattle fed in confinement for slaughter: As in paragraph (e)(1) of this section; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	As in paragraph (e)(1) of this section; see paragraph § 558.355(d) of this chapter. Monensin as provided by No. 000986 in § 510.600(c) of this chapter.	000061
(4) 6.8 to provide 60 to 90 mg/head/day	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(1) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat).	As in paragraph (e)(1) of this section; see §§ 558.342(d) and 558.355(d) of this chapter. Monensin as provided by No. 000986; melengestrol acetate as provided by Nos. 000009 or 021641 in § 510.600(c) of this chapter.	000061 021641
(5) 6.8 to provide 60 to 90 mg/head/day	Monensin 10 to 40, plus tylosin 8 to 10	Cattle fed in confinement for slaughter: As in paragraph (e)(1) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.	As in paragraph (e)(1) of this section; see §§ 558.355(d) and 558.625(c) of this chapter. Monensin and tylosin as provided by No. 000986 in § 510.600(c) of this chapter.	000061

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(6) 6.8 to provide 60 to 90 mg/head/day.	Monensin 10 to 40, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: As in paragraph (e)(1) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*; and for suppression of estrus (heat).	As in paragraph (e)(1) of this section; see §§ 558.342(d), 558.355(d), and 558.625(c) of this chapter. Monensin and tylosin as provided by No. 000986; melengestrol acetate as provided by Nos. 000009 or 021641 in § 510.600(c) of this chapter.	000061 021641

[71 FR 53006, Sept. 8, 2006, as amended at 72 FR 9245, Mar. 1, 2007; 72 FR 6019, Feb. 1, 2008; 73 FR 14385, Mar. 18, 2008; 73 FR 16755, Mar. 31, 2008; 73 FR 18959, Apr. 8, 2008; 73 FR 19432, Apr. 10, 2008; 74 FR 61517, Nov. 25, 2009; 75 FR 11451, Mar. 11, 2010]

§ 558.680 Zoalene.

(a) *Specifications.* Type A medicated article containing 25 percent zoalene.

(b) *Approvals.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.770 of this chapter.

(d) *Conditions of use*—(1) *Chickens and turkeys:*

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
(i) 36.3–113.5 (0.004–0.0125%)..	.....	Replacement chickens; development of active immunity to coccidiosis..	Grower ration not to be fed to birds over 14 weeks of age; as follows:

Growing conditions	Starter ration Grams per ton	Grower ration Grams per ton
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%)

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Arsanilic acid 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation..	Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5..	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation..	As erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable item (i).
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5..	1. Replacement chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation..	Feed for 2 d before stress and 3 to 6 d after stress; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic arsenic; feed as in subtable in item (i).

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	.....	2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation..	Feed for 7 to 14 d; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%) plus erythromycin 185..	Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation and development of active immunity to coccidiosis..	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as erythromycin thiocyanate; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50..	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation..	As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Bacitracin 4 to 50	Replacement chickens: For development of active immunity to coccidiosis; for increased rate of weight gain, improved feed efficiency.	Feed as in subtable in § 558.680(d)(1)(i); grower ration not to be fed to birds over 14 weeks of age. As bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.
	Bacitracin methylene disalicylate 4 to 50 plus roxarsone 22.7 to 45.4.	Replacement chickens: For development of active immunity to coccidiosis; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed as in subtable in § 558.680(d)(1)(i); grower ration not to be fed to birds over 14 weeks of age. Discontinue use 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. As bacitracin methylene disalicylate and roxarsone provided by No. 046573 in § 510.600(c) of this chapter.
	Bacitracin methylene ..... disalicylate 50	Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration as in subtable in this item (i); grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.
	Bacitracin methylene disalicylate 100 to 200.	Replacement chickens; development of active immunity to coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration as in subtable in this item (i). To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.
	Bacitracin 100 to 500.	Replacement chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); development of active immunity to coccidiosis..	As bacitracin zinc; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Chlortetracycline 100 to 200..	Replacement chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline..	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Chlortetracycline 200 to 400..	Replacement chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline..	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Erythromycin 4.6 to 18.5.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis..	As erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Erythromycin 92.5.	1. Replacement chickens, as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis..	Feed for 2 d before stress and 3 to 6 after stress; withdraw 24 hours (h) before slaughter; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	.....	2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis..	Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Erythromycin 185.	Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; development of active immunity to coccidiosis..	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Hygromycin B 8 to 12.	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms (*Ascaris galli*) cecal worms (*Heterakis gallinae*) and capillary worms (*Capillaria obsignate*)..	Grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Penicillin 2.4 to 50.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis..	As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%)..	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation..	As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Roxarsone 22.7 to 45.5 (0.0025% to 0.005%)..	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation..	Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
(ii) 113.5 (0.0125%).	.....	Broiler chickens; prevention and control of coccidiosis..	
	Arsanilic acid 90 (0.01%).	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation..	Withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5..	Broiler chickens; growth prevention and control of coccidiosis; improving pigmentation..	As erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5..	1. Broiler chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation; control of coccidiosis..	Do.
	.....	2. Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza..	Do.
	Arsanilic acid 90 (0.01%) plus erythromycin 185..	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation..	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; as erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50..	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation..	As procaine penicillin; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus bacitracin 4 to 50..	Broiler chickens; prevention and control of coccidiosis; improving pigmentation; growth promotion and feed efficiency..	Withdraw 5 d before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate.
	Bacitracin 4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis..	As bacitracin methylene disalicylate or zinc bacitracin.
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005%)..	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation..	As bacitracin methylene disalicylate or zinc bacitracin; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Bacitracin methylene disalicylate 50.	Broiler chickens; prevention and control of coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.
	Bacitracin methylene disalicylate 100 to 200.	Broiler chickens; prevention and control of coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin..	Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.
	Bacitracin 100 to 500.	Broiler chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); prevention and control of coccidiosis..	As zinc bacitrain.
	Bambermycins 1	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Do not feed to chickens over 14 weeks of age. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Bambermycins 1 plus roxarsone 22.7.	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Do not feed to chickens over 14 weeks of age; feed as sole source of organic arsenic; withdraw 5 days before slaughter. Bambermycins as provided by No. 016592, roxarsone by No. 046573 in § 510.600(c) of this chapter.
	Chlortetracycline 100 to 200.	Broiler chickens; prevention and control of coccidiosis; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline..	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.
	Chlortetracycline 200 to 400.	Broiler chickens; prevention and control of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline..	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.
	Erythromycin 4.6 to 18.5.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis..	As erythromycin thiocyanate.
	Erythromycin 92.5.	1. Broiler chickens; as an aid in the prevention of chronic respiratory disease during period of stress; prevention and control of coccidiosis..	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; as erythromycin thiocyanate.
	.....	2. Broiler chicken; as an aid in the prevention of infectious coryza; prevention and control of coccidiosis..	Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate.
	Erythromycin 185.	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis..	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; as erythromycin thiocyanate.
	Hygromycin B 8 to 12.	Broiler chickens; prevention and control of coccidiosis; control of infestation of large round worms (*Ascaris galli*) cecal worms (*Heterakis gallinae*) and capillary worms (*Capillaria obsignate*) ..	
	Lincomycin 2.	Broiler chickens; increase in rate of weight gain; improved feed efficiency; as an aid in the prevention and control of coccidiosis..	Do not feed to laying chickens; to be fed as the sole ration; as lincomycin hydrochloride monohydrate provided by No. 000009 in § 510.600(c) of this chapter.
	Penicillin 2.4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis..	As procaine penicillin.
	Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005%)..	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation..	Withdraw 5 d before slaughter; as sole source of organic arsenic; as procaine penicillin.
	Roxarsone 22.7 to 45.4 (0.0025 to 0.005%)..	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation..	Withdraw 5 d before slaugher; as sole source of organic arsenic.
(iii) 113.5 to 170.3 (0.0125 to 0.01875%)..	.....	Turkeys; prevention and control of coccidiosis..	For turkeys grown for meat purposes only.
	Arsanilic acid 90(0.01%). ..	do.	Do.
	Bacitracin methylene disalicylate 4–50..	Turkeys; prevention and control of coccidiosis, and increased rate of weight gain and improved feed efficiency..	For turkeys grown for meat purposes only, not to be fed to laying birds, feed continuously as sole ration until 14 to 16 weeks of age.

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Carbarsone (not U.S.P.) 277 to 340.5 (0.025% to 0.0375%)..	Turkeys; prevention and control of coccidiosis; aid in the prevention of blackhead..	For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected and continue as long as prevention of blackhead and prevention and control of coccidiosis is needed; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%)..	Turkeys; growth promotion and feed efficiency; improving pigmentation..	Withdraw 5 d before slaughter; as sole source of organic arsenic.

(2) Zoalene may also be used in combination with roxarsone as in §558.530.

[41 FR 11005, Mar. 15, 1976, as amended at 42 FR 18618, Apr. 8, 1977; 42 FR 20817, Apr. 22, 1977; 42 FR 36995, July 19, 1977; 51 FR 7401, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 8461, Mar. 8, 1990; 57 FR 8403, Mar. 10, 1992; 57 FR 8578, Mar. 11, 1992; 61 FR 35957, July 9, 1996; 63 FR 38750, July 20, 1998; 67 FR 6868, Feb. 14, 2002; 71 FR 16223, Mar. 31, 2006; 71 FR 27958, May 15, 2006; 76 FR 17027, Mar. 28, 2011]

PART 564 [RESERVED]

PART 570—FOOD ADDITIVES

Subpart A—General Provisions

Sec.

Subpart B—Food Additive Safety

AUTHORITY: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

SOURCE: 41 FR 38644, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§570.3 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Department* means the Department of Health and Human Services.

(c) *Commissioner* means the Commissioner of Food and Drugs.

(d) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936 (52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 301–392).

(e) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. *Affecting the characteristics of food* does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture,